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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. STF, LLC, an organization; STATE OF CALIFORNIA ex rel. STF, LLC, an organization, Plaintiff, vs. VIBRANT AMERICA, LLC, a Delaware Limited Liability Company, Defendant.	CASE NO. 3:16-CV-02487-JCS **DEFENDANT'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF MOTION TO DISMISS** Date: July 24, 2020 Time: 9:30 AM Courtroom: F Before the Honorable Joseph C. Spero

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Pursuant to Federal Rule of Evidence 201, and in connection with the concurrently filed Motion to Dismiss Plaintiff-Relator's Complaint, Defendant Vibrant America, LLC ("Defendant") respectfully requests that the Court take judicial notice of the following documents in support of its Motion to Dismiss:

1. A copy of a Centers for Medicare & Medicaid Services ("CMS") Notice issued on April

29, 2020, related to COVID-19, attached hereto as Exhibit A. The Court may take judicial notice of information found on government websites. *See Daniels–Hall v. Nat,l Educ. Ass'n*, 629 F.3d 992, 999 (9th Cir.2010) (taking judicial notice of information found on government websites).

2. Guidance issued by the Department of Health and Human Services Office of Inspector General ("OIG") and the California Department of Public Health cited as support by Relator in its Complaint. The Court may take judicial notice of documents heavily relied on by Relator in its Complaint. *See Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002) (under the doctrine of "incorporation by reference" it is appropriate for a district court to "consider documents that were referenced extensively in the complaint and were accepted by all parties as authentic."). The Court may also take judicial notice of documents posted by government agencies. *See Musgrave v. ICC/Marie Callender's Gourmet Prods. Div.*, 2015 WL 510919, at *3 (N.D. Cal. Feb 5, 2015) ("Documents available through government agency websites are often considered appropriate for judicial notice as documents in the public record not reasonably subject to dispute.").

    a. A copy of the 2005 Advisory Opinion, No. 05-08, issued by OIG on June 6, 2005, is attached hereto as Exhibit B.

    b. A copy of the 2014 Special Fraud Alert, issued by OIG on June 25, 2014, is attached hereto as Exhibit C.

    c. A copy of the 1994 Special Fraud Alert, issued by OIG on December 19, 1994, is attached hereto as Exhibit D.

    d. A copy of the guidance issued by the California Department of Public Health Notice referenced in Relator's Complaint at ¶ 28, is attached hereto as Exhibit E.

3. A copy of Chapter 16 of the Centers for Medicare & Medicaid Services Medicare Claims Processing Manual, is attached hereto as Exhibit F. The Court may take judicial notice of documents issued by government agencies. *See Cty. of Santa Clara v. Astra USA, Inc.*, 401 F.Supp.2d 1022, 1024 (N.D.Cal.2005) (taking judicial notice of information issued in

a report by the Department of Health and Human Services and information posted to its website).

4. A copy of the first page of either the initial Complaint or the Notice of Removal filed in the following dockets: *Riedel v. Bluewave Healthcare Consultants Inc.*, No. 9:15-cv-02485 (D.S.C. June 19, 2015); *Hunter Lab., LLC et al v. Quest Diagnostics Inc. et al*, No. 1:13-cv-01129 (E.D. Va. Sep. 9, 2013); *State of Georgia ex. rel., et al. v. Lab Corp. of America, et al*, No. 1:13-cv-01838 (N.D. Ga. May 31, 2013); *Riedel v. Bos. Heart Diagnostics Corp.*, No. 1:12-cv-01423 (D.D.C. August 28, 2012), is attached hereto as Exhibit G. The Court may take judicial notice of dockets in other federal cases. *See Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006) ("We may take judicial notice of court filings and other matters of public record"); *Headwaters Inc. v. U.S. Forest Serv.*, 399 F.3d 1047, 1051 n.3 (9th Cir. 2005) (taking judicial notice of other dockets).

5. A copy of two printouts from the California Secretary of State Website, is attached hereto as Exhibit H. The Court may take judicial notice of documents from a state agency website. See *Pension Plan for Pension Tr. Fund for Operating Engineers v. Weldway Const.*, Inc., 920 F. Supp. 2d 1034, 1036, n.1 (N.D. Cal. 2013) (taking judicial notice of documents from the California Secretary of State website).

DATED: May 18, 2020

FOLEY & LARDNER LLP
Thomas S. Brown
Judith A. Waltz
Lori A. Rubin

/s/ *Thomas S. Brown*
Thomas S. Brown
Attorneys for Defendant
Vibrant America, LLC

EXHIBIT A

Laboratories: Medicare Flexibilities to Fight COVID-19

Since the beginning of the COVID-19 Public Health Emergency, the Trump Administration has issued an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. These temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) expand the healthcare system workforce by removing barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states; 2) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

Medicare COVID-19 Diagnostic Testing

- *Laboratory Specimen Collection from Patient's Home:* Medicare will pay when laboratories send trained technicians to collect a sample from a homebound beneficiary or a non-hospital inpatient for COVID-19 diagnostic testing. Medicare will pay a specimen collection fee and for the travel. The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a non-covered stay in a SNF or whose samples are collected by a laboratory on behalf of an HHA is $25.46.

- *Practitioner Payment for Specimen Collection:* Practitioners can be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT code 99211. In light of the public health emergency, Medicare will recognize this code to be billed for all patients, not just established patients. This approach may help physician practices to operate testing sites during the PHE.

- Hospital outpatient departments can be paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19])), any specimen source retroactive to March 1, 2020. The service would be paid as conditionally packaged when furnished with another payable service under the OPPS. This approach helps hospitals to operate testing sites during the PHE. Medicare will pay a national rate of roughly $23 for C9803 when it is not billed with a separately payable hospital outpatient service.

- *Home Health Specimen Lab Collection*: If a patient is already receiving Medicare home health services, the home health nurse, during an otherwise covered visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.

- *RHC/FQHC Visiting Nurse Lab Specimen Collection*: If a visiting nurse has an otherwise covered RHC or FQHC visit, they can obtain a sample to send to the laboratory for COVID-19 diagnostic testing.

- *COVID-19 Diagnostic Testing:* Practitioners can be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT code 99211. In light of the public health emergency, Medicare will recognize this code to be billed for all patients, not just established patients. This approach helps physician practices to operate testing sites during the PHE.

- *Physician or Practitioner Order for COVID-19 tests:* Medicare will not require an order from a treating physician or nonphysician practitioner as a condition of Medicare coverage of COVID-19 and other related diagnostic laboratory testing during the PHE. CMS similarly removed these requirements for an influenza virus diagnostic laboratory test and any other diagnostic laboratory test that is necessary to establish or rule out a COVID-19 diagnosis. FDA requirements for an order and state requirements around ordering diagnostic tests would still apply. CMS has also removed certain documentation and recordkeeping requirements associated with orders for COVID-19 diagnostic tests as these requirements would not be relevant in the absence of an order. CMS still requires laboratories to furnish the results of COVID-19 tests to the beneficiary. Consistent and regular reporting of all testing results to local officials is critical to public health management of the pandemic, we would expect any clinician or laboratory receiving results to report those results promptly consistent with state and local public health requirements, typically within 24 hours.

- *Pharmacists:* Medicare will pay for COVID-19 tests performed by pharmacists as part of a laboratory enrolled in Medicare. A pharmacist also may furnish basic clinical services, such as specimen collection, when performed under contract with a doctor or practitioner, in accordance with a pharmacist's scope of practice and state law. As auxiliary personnel, pharmacists can provide services incident to the professional services of a physician or nonphysician practitioner who bills Medicare Part B under the Physician Fee Schedule (PFS) services, if incident to rules are met and payment for the services is not made under Medicare Part D. The services must be provided in accordance with the pharmacists' scope of practice and applicable state law. This includes assessing and collecting specimens for COVID-19 diagnostic tests. A pharmacy that acquires a CLIA certificate can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests it is authorized to perform under its CLIA certificate.

- *Antibody (serology) tests*: FDA-authorized COVID-19 serology testing is a Medicare covered diagnostic test for patients that may with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. The outcome of the serology test may change the health care decisions made by a patient and their practitioner.

Patients Over Paperwork

- *"Stark Law" Waivers:* The physician self-referral law (also known as the "Stark Law") prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship. On March 30, 2020, CMS issued blanket waivers of certain provisions of the Stark Law regulations. These blanket waivers apply to financial relationships and referrals that are related to the COVID-19 emergency. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 Purposes, as defined in the blanket waiver document. Under the waivers, CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. These flexibilities include:

    - Hospitals and other health care providers can pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties may pay below fair market value to rent equipment or purchase items or services. For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party. Or, a hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.

    - Health care providers can support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.

    - Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.

    - Health care providers may offer certain items and services that are solely related to COVID-19 Purposes (as defined in the waivers), even when the provision of the items

or services would exceed the annual non-monetary compensation cap. For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.

- Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.

- Some of the restrictions regarding when a group practice can furnish medically necessary designated health services (DHS) in a patient's home are loosened. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS.

- Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.

- *Accelerated/Advance Payments*: In order to provide additional cash flow to healthcare providers and suppliers impacted by COVID-19, CMS expanded and streamlined the Accelerated and Advance Payments Program, which provided conditional partial payments to providers and suppliers to address disruptions in claims submission and/or claims processing subject to applicable safeguards for fraud, waste and abuse. Under this program, CMS made successful payment of over $100 billion to healthcare providers and suppliers. As of April 26, 2020, CMS is reevaluating all pending and new applications for the Accelerated Payment Program and has suspended the Advance Payment Program, in light of direct payments made available through the Department of Health & Human Services' (HHS) Provider Relief Fund. Distributions made through the Provider Relief Fund do not need to be repaid. For providers and suppliers who have received accelerated or advance payments related to the COVID-19 Public Health Emergency, CMS will not pursue recovery of these payments until 120 days after the date of payment issuance. Providers and suppliers with questions regarding the repayment of their accelerated or advance payment(s) should contact their appropriate Medicare Administrative Contractor (MAC).

- *Provider Enrollment*: CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:
    - Waive certain screening requirements.
    - Postpone all revalidation actions.
    - Expedite any pending or new applications from providers.

Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;

- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);

- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;

- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.

- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Clinical Laboratory Improvement Act (CLIA) Guidance

- CMS will exercise enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location

- CMS will expedite CLIA certificate application review and processing to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency.

- CMS is allowing laboratories within a hospital/University Hospital Campus to hold a single certificate for the laboratory sites within the same physical location or street address.

- CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples. CLIA regulations are not prescriptive about the type of transport device, for example, specimen collection swabs and viral transport media, that laboratories use to collect the specimens needed to perform a test. CLIA only requires that the laboratory follow manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. CLIA is not prescriptive as to how the study is performed; the Laboratory Director is responsible for defining the validation parameters.

Additional Guidance

- The Interim Final Rules and waivers can be found at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency can be found at: https://www.cms.gov/files/document/qso-20-21-clia.pdf-0

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: June 6, 2005

Posted: June 13, 2005

[name and address redacted]

Re: OIG Advisory Opinion No. 05-08

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your laboratory's proposal to provide free blood collection supplies to physicians and pay those physicians for the collection of blood samples (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate

prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

[Name redacted] (the "Lab") provides laboratory testing services in [state redacted]. Currently, physicians send their patients to the Lab, which performs blood draws and laboratory tests on-site. The Lab submits claims for these blood draws and blood tests to patients' insurers, including Federal health care programs. Some of the referring physicians have told the Lab that they would like to draw their patients' blood during office visits, rather than send their patients to the Lab for blood draws, and have the Lab pick up the specimens from the physicians' offices. These physicians have requested that the Lab: (1) provide blood drawing supplies at no charge to the physicians; and (2) pay the physicians a per-patient amount for the physicians' services in collecting the blood specimens (collectively, the "blood draw remuneration").

Medicare pays $3 per patient encounter for specimen collection fees charged by physicians, independent laboratories, or hospital laboratories for the services and supplies they use in collecting blood samples, payable only to the person or entity that actually extracted the specimen from the patient. See Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 16, section 60.1 - 60.1.4, available at http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp. Under the Proposed Arrangement, the amount the Lab would pay to each physician would be determined according to negotiations between the Lab and the physician, but would likely be between $3 and $6 for each patient receiving a blood draw, although the payment would be made no more than once each day for each patient. The Lab states that it wishes to enter into the Proposed Arrangement, because competing laboratories are paying referring physicians to perform blood draws.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the physicians will be paid on a per-patient basis, and, thus, the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

B. Analysis

The Proposed Arrangement, by which the Lab would provide referring physicians with free blood drawing supplies and payments for blood drawing services that may exceed what the Lab receives for such services and supplies from Medicare, would clearly implicate the anti-kickback statute.

There is a substantial risk that the Lab would be offering the blood draw remuneration to the physicians in exchange for referrals to the Lab. Under the Proposed Arrangement, the physicians could receive up to twice the $3 amount Medicare pays for blood specimen collection, plus any necessary blood-drawing supplies free of charge. Particularly when viewed in the aggregate, this compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the Lab. Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory, particularly in the circumstances presented here.

Based on the facts presented here, it appears that the physicians may well be soliciting the blood draw remuneration as a condition of sending new or continued referrals to the Lab. In addition, we cannot exclude the possibility that the Lab may be offering the blood draw remuneration to the physicians with the intent to induce new or continued referrals to the Lab, especially in light of the Lab's representation that the Proposed Arrangement is a reaction to competitors' arrangements to provide such blood draw remuneration to referring physicians. These competitor arrangements similarly may run afoul of the anti-kickback statute.

Furthermore, the Proposed Arrangement essentially would give the physicians the opportunity to earn a fee otherwise earned by the Lab. Because the physicians would receive a portion of the Lab's reimbursement for blood tests resulting from the physicians' referrals, the physicians have a strong incentive to order more blood tests. As a result, there is a risk of overutilization and inappropriate higher costs to the Federal health care programs. We discern no safeguards in the Proposed Arrangement to rebut the inference or reduce the risk that the blood draw remuneration would be intended to induce referrals.

Finally, we note that any specimen collection claims submitted by the Lab to Medicare for blood draws performed by the referring physicians would be improper claims and would implicate the Federal False Claims Act, at 31 U.S.C. § 3729, and the Civil Monetary Penalties Law, at section 1128A(a)(1) of the Act. As noted, Medicare pays only the person or entity that actually extracted the specimen from the patient. As such, Medicare rules would prohibit the Lab from billing Medicare for blood collection services rendered by the

referring physicians. In addition, while under certain conditions physicians can bill Medicare directly for collecting blood specimens,[1] if the Lab were to pay a physician to perform a blood draw, the physician would be impermissibly "double dipping" if the physician also billed Medicare for that blood draw.[2]

Accordingly, based on the totality of facts and circumstances, we conclude that the Proposed Arrangement poses a substantial risk of program fraud and abuse.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

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[1]Physician charges for specimen collection fee are allowed when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and (2) it is the customary practice of the physician performing such services to bill separate charges for them. See Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 16, section 60.1.1.

[2]Only one collection fee is allowed per patient encounter, regardless of the number of blood specimens drawn. See id. at section 60.1.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

EXHIBIT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: Laboratory Payments to Referring Physicians

June 25, 2014

Summary

This Special Fraud Alert addresses compensation paid by laboratories to referring physicians and physician group practices (collectively, physicians) for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database. OIG has issued a number of guidance documents and advisory opinions addressing the general subject of remuneration offered and paid by laboratories to referring physicians, including the 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Laboratory Services, the OIG Compliance Program Guidance for Clinical Laboratories, and Advisory Opinion 05-08. In these and other documents, we have repeatedly emphasized that providing free or below-market goods or services to a physician who is a source of referrals, or paying such a physician more than fair market value for his or her services, could constitute illegal remuneration under the anti-kickback statute. This Special Fraud Alert supplements these prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that we believe present a substantial risk of fraud and abuse under the anti-kickback statute.

I. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

II. Remuneration From Laboratories to Referring Physicians

Arrangements between referring physicians and laboratories historically have been subject to abuse and were the topic of one of the OIG's earliest Special Fraud Alerts.[1] In that Special Fraud Alert, we stated that, "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." More generally, we have, on various occasions, repeated our position that arrangements providing free or below-market goods or services to actual or potential referral sources are suspect and may violate the anti-kickback statute, depending on the circumstances.[2]

Likewise, when a laboratory pays a physician more than fair market value for the physician's services or for services the laboratory does not actually need or for which the physician is otherwise compensated, the anti-kickback statute is implicated. Such payments are suspect under the anti-kickback statute because of the implication that one purpose of the payments is to induce the physician's Federal health care program referrals. OIG also historically has been concerned with arrangements in which the amounts paid to a referral source take into account the volume or value of business generated by the referral source.

Arrangements in which laboratories provide free or below-market goods or services to physicians or make payments to physicians that are not commercially reasonable in the absence of Federal health care program referrals potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because such transfers of value may induce physicians to order tests from a laboratory that provides them with remuneration, rather than the laboratory that provides the best, most clinically appropriate service. Such transfers of value also may induce physicians to order more laboratory tests than are medically necessary, particularly when the transfers of value are tied to, or take into account, the volume or value of business generated by the physician. We are particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically is made or strongly influenced by the physician, with little or no input from patients.

Although physicians may order any tests they believe are appropriate to diagnose and treat their patients, Medicare will pay for laboratory tests only if they meet Medicare coverage criteria and are reasonable and necessary.[3] Moreover, claims that include items or services resulting from a violation of the anti-kickback statute are not payable by Medicare and may constitute false claims under the False Claims Act, even if the items or services are medically necessary.[4] OIG recognizes that the lawfulness of any particular arrangement under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by the arrangement's characteristics, including its legal structure, its operational safeguards, and the actual conduct of

[1] Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), *reprinted at* 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).
[2] *See, e.g.*, Advisory Opinion 11-07, p. 7.
[3] Section 1862(a)(1)(A) of the Act.
[4] 31 U.S.C. 3729 et seq.

the parties to the arrangement. Nonetheless, we believe the following types of arrangements between laboratories and physicians are suspect under the anti-kickback statute.

A. Blood-Specimen Collection, Processing, and Packaging Arrangements

OIG has become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patients' specimens. This Special Fraud Alert addresses arrangements under which laboratories pay physicians, either directly or indirectly (such as through an arrangement with a marketing or other agent) to collect, process, and package patients' blood specimens (Specimen Processing Arrangements).[5] Specimen Processing Arrangements typically involve payments from laboratories to physicians for certain specified duties, which may include collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens so that they are not damaged in transport. Payments under Specimen Processing Arrangements typically are made on a per-specimen or per-patient-encounter basis and often are associated with expensive or specialized tests.

Medicare allows the person who collects a specimen to bill Medicare for a nominal specimen collection fee in certain circumstances, including times when the person draws a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacuum tube to draw the specimen).[6] Medicare allows such billing only when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.[7] Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn.[8] Physicians who satisfy the specimen collection fee criteria and choose to bill Medicare for the specimen collection must use Current Procedural Terminology (CPT) Code 36415, "Routine venipuncture – Collection of venous blood by venipuncture."[9, 10]

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[5] The same principles described in this Special Fraud Alert apply to arrangements that are similar or analogous to Specimen Processing Arrangements, including arrangements under which clinical laboratories pay physicians to collect and package patients' buccal swabs or urine specimens or provide free or below-market point of care urine testing cups to health care providers who use the cups to perform billable in-office testing.

[6] Section 1833(h)(3) of the Act; *Medicare Claims Processing Manual*, CMS Pub. 100-04, Chapter 16, section 60.1.

[7] *Medicare Claims Processing Manual*, CMS Pub. 100-04, Chapter 16, section 60.1.1.

[8] *Medicare Claims Processing Manual*, CMS Pub. 100-04, Chapter 16, section 60.1.

[9] **The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2014 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

[10] CPT code 36415 is included on the clinical laboratory fee schedule. As of the date of issuance of this Special Fraud Alert, Medicare pays a specimen collection fee of $5 for samples collected from individuals in skilled nursing facilities and by laboratories on behalf of home health agencies and a specimen collection fee of $3 for all other samples. *See, e.g.*, Clinical Laboratory Fee Schedule – January 2014 Release, *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html; *specifically* CLAB2014.EffJan1.Full.xlsx (the 2014 Clinical Diagnostic Laboratory Fee Schedule), *available at* http://www.cms.gov/apps/ama/license.asp?file=/ClinicalLabFeeSched/downloads/14CLAB.zip; and Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216(a), 128 Stat. 1040 and 1053-1059 (to be codified at 42 U.S.C. § 1395m-1(b)(5)) (2014).

Medicare reimburses physicians for processing and packaging specimens for transport to a clinical laboratory through a bundled payment.[11] Physicians who wish to report the work involved in preparing a specimen to send to a laboratory may use CPT code 99000, "Handling and/or conveyance of specimen for transfer from the office to a laboratory."[12] CPT code 99000 is intended to reflect the work involved to prepare a specimen prior to sending it to a laboratory, including centrifuging a specimen, separating serum, labeling tubes, packing the specimens for transport, filling out laboratory forms, and supplying necessary insurance information and other documentation.[13]

The anti-kickback statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of the statute occurs depends on the intent of the parties—the anti-kickback statute prohibits the knowing and willful payment of such amounts if even one purpose of the payment is to induce or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered. The probability that a payment is for an illegitimate purpose is increased, however, if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare.

When determining the fair market value of a physician's services, a clinical laboratory should consider whether the services for which it may compensate the physician have been, or may be, paid for, including through a bundled payment, by Medicare. Additionally, the laboratory should consider whether payment is appropriate at all; if the services for which the laboratory intends to compensate the physician are paid for by a third party through other means, such as payments intended to reimburse the physician for overhead expenses, any payment by the laboratory to the physician may constitute double payment for the physician's services and, consequently, provide evidence of unlawful intent.

Characteristics of a Specimen Processing Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment.

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[11] Since 2003, CPT code 99000 has been listed as a "Bundled Code" in the Medicare Physician Fee Schedule (MPFS). *See, e.g.*, Physician Fee Schedule – January 2014 Release, *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU14A.html; *specifically* PPRRVU14_V1219.xlsx (the 2014 National Physician Fee Schedule Relative Value File) and RVUPUF14.pdf (containing information on services covered by the MPFS, including fee schedule status indicators), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVU14A.zip. A "Bundled Code" means that "[p]ayment for covered services are always bundled into payment for other services not specified." RVUPUF14.pdf, Attachment A.

[12] Even though physicians are not directly reimbursed under this code, as they are with CPT code 36145, they may choose to report this CPT code so that the costs associated with the services they perform are taken into account in CMS's calculation of the practice expense component of a procedure's relative value unit. *See* Overview, MPFS, *available at* https://www.cms.gov/apps/physician-fee-schedule/overview.aspx.

[13] *Coding Clarification: Handling and/or Conveyance of Specimen for Transfer from the Physician's Office to a Laboratory*, CPT Assistant (AMA), Oct. 1999, at 11.

- Payment is for services for which payment is also made by a third party, such as Medicare.
- Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.
- Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
- Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.
- Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

OIG's concerns regarding Specimen Processing Arrangements are not abated when those arrangements apply only to specimens collected from non-Federal health care program patients. Arrangements that "carve out" Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Because physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency, Specimen Processing Arrangements that carve out Federal health care program business may nevertheless be intended to influence physicians' referrals of Federal health care program business to the offering laboratories.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" arrangement, physicians who enter into Specimen Processing Arrangements with laboratories also may be at risk under the statute.

B. Registry Payments

OIG has become aware of arrangements under which clinical laboratories are establishing, coordinating, or maintaining databases, either directly or through an agent, purportedly to collect data on the demographics, presentation, diagnosis, treatment, outcomes, or other attributes of patients who have undergone, or who may undergo, certain tests performed by the offering laboratories. Typically these are specialized and expensive tests paid for by Federal health care programs. This Special Fraud Alert addresses such "Registries" or "Registry Arrangements," whether they are referred to as "registries" or "observational outcomes databases" or by other terminology.

Laboratories that participate in Registry Arrangements often assert that they are intended to advance clinical research to promote treatment, to provide physicians with valuable clinical

knowledge for patients with similar disease profiles, and to provide other benefits to physicians or the health care industry generally. Registry Arrangements may take various forms; however, they typically involve payments from laboratories to physicians for certain specified duties, including, by way of example only, submitting patient data to be incorporated into the Registry, answering patient questions about the Registry, and reviewing Registry reports.

Registry Arrangements may induce physicians to order medically unnecessary or duplicative tests, including duplicative tests performed for the purpose of obtaining comparative data, and to order those tests from laboratories that offer Registry Arrangements in lieu of other, potentially clinically superior, laboratories. OIG recognizes that whether any particular Registry Arrangement violates the anti-kickback statute depends on the intent of the parties to the arrangement. Payments from a laboratory to a physician to compensate the physician for services related to data collection and reporting may be reasonable in certain limited circumstances. However, the anti-kickback statute prohibits the knowing and willful payment of such compensation if even one purpose of the payments is to induce or reward referrals of Federal health care program business.

Characteristics of a Registry Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:

- The laboratory requires, encourages, or recommends that physicians who enter into Registry Arrangements perform the tests with a stated frequency (e.g., four times per year) to be eligible to receive, or to not receive a reduction in, compensation.
- The laboratory collects comparative data for the Registry from, and bills for, multiple tests that may be duplicative (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise are not reasonable and necessary.
- Compensation paid to physicians pursuant to Registry Arrangements is on a per-patient or other basis that takes into account the value or volume of referrals.
- Compensation paid to physicians pursuant to Registry Arrangements is not fair market value for the physicians' efforts in collecting and reporting patient data.
- Compensation paid to physicians pursuant to Registry Arrangements is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians' efforts.
- The laboratory offers Registry Arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it exclusively performs.
- When a test is performed by multiple laboratories, the laboratory collects data only from the tests it performs.
- The tests associated with the Registry Arrangement are presented on the offering laboratory's requisition in a manner that makes it more difficult for the ordering physician to make an independent medical necessity decision with regard to each test for which the laboratory will bill (e.g., disease-related panels).

Other characteristics not listed above may increase the risk of fraud and abuse associated with a Registry Arrangement or provide evidence of unlawful intent. For example, the risk of fraud and abuse would be particularly high if a laboratory were to pay, and collect data for its Registry from, only a subset of physicians who were selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty, or other relevant attribute.

The anti-kickback statute does not prohibit laboratories from engaging in, or paying compensation for, legitimate research activities. However, claims that Registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent. Even legitimate actions taken to substantiate such claims, including, for example, retaining an independent Institutional Review Board to develop study protocols and participation guidelines, will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals. Furthermore, for the reasons set forth in section II.A above, OIG's concerns regarding Registry Arrangements are not abated when those arrangements apply only to data collected from tests performed on non-Federal health care program patients' specimens.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" arrangement, physicians who enter into Registry Arrangements with laboratories also may be at risk under the statute.

III. Conclusion

OIG is concerned about the risks that Specimen Processing Arrangements and Registry Arrangements pose under the anti-kickback statute. This Special Fraud Alert reiterates our longstanding concerns about payments from laboratories to physicians in excess of the fair market value of the physicians' services and payments that reflect the volume or value of referrals of Federal health care program business. Should interested parties continue to have questions about the structure of a particular Specimen Processing Arrangement or Registry Arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.

To report suspected fraud involving Registry Arrangements, Specimen Processing Arrangements, or similar arrangements, contact the OIG Hotline at https://forms.oig.hhs.gov/hotlineoperations/ or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

EXHIBIT D

[Federal Register: December 19, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Publication of OIG Special Fraud Alerts

AGENCY: Office of Inspector General, HHS.
ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the 5 previously-developed Special Fraud Alerts issued directly to the health care provider community by the HHS Office of Inspector General (OIG). In keeping with the OIG's goal and intent of publicizing its concern about possible widespread and abusive health care industry practices, and seeking wider dissemination of this information to the general public, we are republishing the main content of these Special Fraud Alerts in the Federal Register. This notice also serves to alert the general public of our intention to publish all future OIG Special Fraud Alerts in this same manner, in addition to the current method used to distribute this material to Medicare and State health care program providers.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Legislation, Regulations and Public Affairs Staff, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Use of Fraud Alerts by the OIG

Over the years, the OIG has used fraud alerts as a vehicle to identify fraudulent and abusive practices within the health care industry. The majority of these fraud alerts are disseminated internally to the OIG's Office of Investigations and other agencies within the Department. However, the OIG has also developed and issued Special Fraud Alerts intended for extensive distribution directly to the health care provider community.

Special Fraud Alerts

Since 1988, the OIG has issued 5 ``Special Fraud Alerts'' addressing specific trends of health care fraud and certain practices of an industry-wide character. Specifically, the OIG Special Fraud Alerts have served to provide general guidance to the health care industry on violations of Federal law (including various aspects of the anti-kickback statute), as well as to provide additional insight to the Medicare carrier fraud units in identifying health care fraud schemes.

In developing these Special Fraud Alerts, the OIG relies on a number of sources, such as studies or management and program evaluations conducted by the OIG's Office of Evaluation and Inspections. In addition, the OIG may consult with experts in the subject field, including those within the OIG, other agencies of the

Department, other Federal and State agencies, and from those in the health care industry.

The Nature of Past Special Fraud Alerts

For the most part, the OIG Special Fraud Alerts have been reserved for national trends in health care fraud and have addressed potential violations of the Medicare and State health care programs' anti-kickback statute. The Special Fraud Alerts have addressed the following topic areas that could violate the anti-kickback statute:

- Joint venture arrangements;
- Routine waiver of Medicare Part B copayments and deductibles;
- Hospital incentives to referring physicians;
- Prescription drug marketing practices;
- Arrangements for the provision of clinical laboratory services.

II. Federal Register Publication of Special Fraud Alerts

In the past, the OIG has always printed and distributed copies of these Special Fraud Alerts directly to all Medicare program providers. While the OIG Special Fraud Alerts have been designed to be available to all affected program providers, we believe it is useful to publicize these various issues and concerns involving potential abusive health care industry practices to a more widespread audience. For this reason, we are using this Federal Register notice as a vehicle to reprint the substance of the 5 previously-issued Special Fraud Alerts cited above. It is our intention to use this same Federal Register form for publishing future Special Fraud Alerts developed by the OIG.

Because each of the previously-developed Special Fraud Alerts contained a similar brief narrative as to the nature of the OIG and a description of the Medicare and Medicaid anti-kickback statute, we will first summarize and set out this material in one section, as it is germane to all 5 subject issuances. Following that will be the main body and content of each of the Special Fraud Alerts. Lastly, we have provided the general information set forth in each of these Special Fraud Alerts addressing information on how to report information on suspected violations.

The OIG Special Fraud Alerts

A. General Background

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections. To help reduce fraud in the Medicare and Medicaid programs, the OIG is actively investigating violations of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. Section 1320a-7b(b).

What Is the Medicare and Medicaid Anti-Kickback Law?

Among its provisions, the anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or in kind to induce, or in return for:

A. Referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program; or

B. Purchasing, leasing or ordering , or arranging for or recommending purchasing, leasing or ordering, any goods, facility, service or item payable under the Medicare or Medicaid program.

Violators are subject to criminal penalties, or exclusion from participation in the Medicare and Medicaid programs, or both. In 1987, section 14 of the Medicare and Medicaid Patient and Program Protection Act, PL 100-93, directed this Department to promulgate ``safe harbor'' regulations, in order to provide health care providers a mechanism to assure them that they will not be prosecuted under the anti-kickback statute for engaging in particular practices. The Department published 11 final ``safe harbor'' regulations on July 29, 1991 (42 CFR 1001.952, 56 FR 35952), and two more on November 5, 1992 (42 CFR 1001.952, 57 FR 52723). The scope of the anti-kickback statute is not expanded by the ``safe harbor'' regulations; these regulations give those in good faith compliance with a ``safe harbor'' the assurance that they will not be prosecuted under the anti-kickback statute.

B. Special Fraud Alert: Joint Venture Arrangements
(Issued August 1989)

The Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called ``joint ventures.'' A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. Of course, there may be legitimate reasons to form a joint venture, such as raising necessary investment capital. However, the Office of Inspector General believes that some of these joint ventures may violate the Medicare and Medicaid anti-kickback statute.

Under these suspect joint ventures, physicians may become investors in a newly formed joint venture entity. The investors refer their patients to this new entity, and are paid by the entity in the form of ``profit distributions.'' These subject joint ventures may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures.

The questionable features of these suspect joint ventures may be reflected in three areas:

(1) The manner in which investors are selected and retained;
(2) The nature of the business structure of the joint venture; and
(3) The financing and profit distributions.

Suspect Joint Ventures: What To Look For

To help you identify these suspect joint ventures, the following are examples of questionable features, which separately or taken together may result in a business arrangement that violates the anti-

kickback statute. Please note that this is not intended as an exhaustive list, but rather gives examples of indicators of potentially unlawful activity.

Investor

- Investors are chosen because they are in a position to make referrals.

- Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals.

- Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an ``acceptable'' level of referrals.

- The joint venture tracks its sources of referrals, and distributes this information to the investors.

- Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire.

- Investment interests may be nontransferable.

Business Structure

- The structure of some joint ventures may be suspect. For example, one of the parties may be an ongoing entity already engaged in a particular line of business. That party may act as the reference laboratory or DME supplier for the joint venture. In some of these cases, the joint venture can be best characterized as a ``shell.''

- In the case of a shell laboratory joint venture, for example:

--It conducts very little testing on the premises, even though it is Medicare certified.
--The reference laboratory may do the vast bulk of the testing at its central processing laboratory, even though it also serves as the ``manager'' of the shell laboratory.
--Despite the location of the actual testing, the local ``shell'' laboratory bills Medicare directly for these tests.

- In the case of a shell DME joint venture, for example:
--It owns very little of the DME or other capital equipment; rather the ongoing entity owns them.
--The ongoing entity is responsible for all day-to-day operations of the joint venture, such as delivery of the DME and billing.

Financing and Profit Distribution

- The amount of capital invested by the physician may be disproportionately small and the returns on investment may be disproportionately large when compared to a typical investment in a new

business enterprise.

• Physician investors may invest only a nominal amount, such as $500 to $1500.

• Physician investors may be permitted to ``borrow'' the amount of the ``investment'' from the entity, and pay it back through deductions from profit distributions, thus eliminating even the need to contribute cash to the partnership.

• Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year.

C. Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B
(Issued May 1991)

To help reduce fraud in the Medicare program, the Office of Inspector General is actively investigating health care providers, practitioners and suppliers of health care items and services who (1) are paid on the basis of charges\1\ and (2) routinely waive (do not bill) Medicare deductible and copayment charges to beneficiaries for items and services covered by the Medicare program.

\1\This fraud alert is not intended to address the routine waiver of copayments and deductibles by providers, practitioners or suppliers who are paid on the basis of costs or diagnostic related groups. The fact that these types of services are not discussed in this fraud alert should not be interpreted to legitimize routine waiver of deductibles and copayments with respect to these payment methods. Also, it does not apply to a waiver of any copayment by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act.

What Are Medicare Deductible and Copayment Charges?

The Medicare ``deductible'' is the amount that must be paid by a Medicare beneficiary before Medicare will pay for any items or services for that individual. Currently, the Medicare Part B deductible is $100 per year.

``Copayment'' (``coinsurance'') is the portion of the cost of an item or service which the Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance is generally 20 percent of the reasonable charge for the item or service. Typically, if the Medicare reasonable charge for a Part B item or service is $100, the Medicare beneficiary (who has met his [or her] deductible) must pay $20 of the physician's bill, and Medicare will pay $80.

Why Is it Illegal for ``Charged-Based'' Providers, Practitioners and Suppliers to Routinely Waive Medicare Copayment and Deductibles?

Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.

A ``charge-based'' provider, practitioner or supplier is one who is paid by Medicare on the basis of the ``reasonable charge'' for the item or service provided. 42 U.S.C. 1395u(b)(3); 42 CFR 405.501. Medicare

typically pays 80 percent of the reasonable charge. 42 U.S.C. 1395l(a)(1). The criteria for determining what charges are reasonable are contained in regulations, and include an examination of (1) the actual charge for the item or service, (2) the customary charge for the item or service, (3) the prevailing charge in the same locality for similar items or services. The Medicare reasonable charge cannot exceed the actual charge for the item or service, and may generally not exceed the customary charge or the highest prevailing charge for the item or service. In some cases, the provider, practitioner or supplier will be paid the lesser of his [or her] actual charge or an amount established by a fee schedule.

A provider, practitioner or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge. For example, if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80. Medicare should be paying 80 percent of $80 (or $64), rather than 80 percent of $100 (or $80). As a result of the supplier's misrepresentation, the Medicare program is paying $16 more than it should for this item.

In certain cases, a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles also could be held liable under the Medicare and Medicaid anti-kickback statute. 42 U.S.C. 1320a-7b(b). The statute makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.

At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.

One important exception to the prohibition against waiving copayments and deductibles is that providers, practitioners or suppliers may forgive the copayment in consideration of a particular patient's financial hardship. This hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made. Otherwise, claims submitted to Medicare mat violate the statutes discussed above and other provisions of the law.

What Penalties Can Someone Be Subject to for Routinely Waiving Medicare Copayments or Deductibles?

Whoever submits a false claim to the Medicare program (for example, a claim misrepresents an actual charge) may be subject to criminal, civil or administrative liability for making false statements and/or submitting false claims to the Government. 18 U.S.C. 287 and 1001; 31 U.S.C. 3729; 42 CFR 1320a-7a). Penalties can include imprisonment, criminal fines, civil damages and forfeitures, civil monetary penalties and exclusion from Medicare and the State health care programs.

In addition, anyone who routinely waives copayments or deductibles can be criminally prosecuted under 42 U.S.C. 1320a-7b(b), and excluded

from participating in Medicare and the State health care programs under the anti-kickback statute. 42 U.S.C. 1320a-7(b)(7).

Finally, anyone who furnishes items or services to patient substantially in excess of the needs of such patients can be excluded from Medicare and the State health care programs. 42 U.S.C. 1320a-7(b)(6)(B).

Indications of Improper Waiver of Deductibles and Copayments

To help you identify charge-based providers, practitioners or suppliers who routinely waive Medicare deductibles and copayments, listed below are some suspect marketing practices. Please note that this list is not intended to be exhaustive but, rather, to highlight some indicators of potentially unlawful activity.

- Advertisements which state: ``Medicare Accepted As Payment in Full,'' ``Insurance Accepted As Payment in Full,'' or ``No Out-Of-Pocket Expense.''

- Advertisements which promise that ``discounts'' will be given to Medicare beneficiaries.

- Routine use of ``Financial hardship'' forms which state that the beneficiary is unable to pay the coinsurance/deductible (i.e., there is no good faith attempt to determine the beneficiary's actual financial condition).

- Collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance (``Medigap'') coverage (i.e., the items or services are ``free'' to the beneficiary).

- Charges to Medicare beneficiaries which are higher than those made to other persons for similar services and items (the higher charges offset the waiver of coinsurance.)

- Failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals).

- ``Insurance programs'' which cover copayments or deductibles only for items or services provided by the entity offering the insurance. The ``insurance premium'' paid by the beneficiary is insignificant and can be as low as $1 a month or even $1 a year. These premiums are not based upon actuarial risks, but instead are a sham used to disguise the routine waiver of copayments and deductibles.

D. Special Fraud Alert: Hospital Incentives to Physicians (Issued May 1992)

Why Do Hospitals Provide Economic Incentives to Physicians?

As many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, physician incentives (sometimes referred to as ``practice enhancements'') are becoming increasingly common. Some physicians actively solicit such incentives. These incentives may result in reductions in the physician's professional expenses or an increase in his or her revenues. In exchange, the physician is aware that he or she is often expected to refer the majority, if not all, of his or her patients to the hospital providing the incentives.

Why Is it Illegal for Hospitals to Provide Financial Incentives to Physicians for Their Referrals?

The Office of Inspector General has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are implicated by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid. In addition, they are not protected under the existing ``safe harbor'' regulations.

These incentive programs can interfere with the physician's judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to overuse inappropriately the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient.

Suspect Hospital Incentive Arrangements--What To Look For

To help identify suspect incentive arrangements, examples of practices which are often questionable are listed [below]. Please note that this list is not intended to be exhaustive but, rather, to suggest some indicators of potentially unlawful activity.

- Payment of any sort of incentive by the hospital each time a physician refers a patient to the hospital.

- The use of free or significantly discounted office space or equipment (in facilities usually located close to the hospital).

- Provision of free or significantly discounted billing, nursing or other staff services.

- Free training for a physician's office staff in such areas as management techniques, CPT coding and laboratory techniques.

- Guarantees which provide that, if the physician's income fails to reach a predetermined level, the hospital will supplement the remainder up to a certain amount.

- Low-interest or interest-free loans, or loans which may be ``forgiven'' if a physician refers patients (or some number of patients) to the hospital.

- Payment of the cost of a physician's travel and expenses for conferences.

- Payment for a physician's continuing education courses.

- Coverage on hospitals' group health insurance plans at an inappropriately low cost to the physician.

- Payment for services (which may include consultations at the hospital) which require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services rendered.

Financial incentive packages which incorporate these or similar features may be subject to prosecution under the Medicare and Medicaid anti-kickback statute, if one of the purposes of the incentive is to influence the physician's medical decision as to where to refer his or her patients for treatment.

E. Special Fraud Alert: Prescription Drug Marketing Schemes (Issued August 1994)

How Does the Anti-Kickback Law Relate to Prescription Drug Marketing Schemes?

In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. Prescription drugs supplied under one of these programs are often reimbursed under Medicaid. Among the specific activities, which the OIG has identified, are the following actual cases:

- A ``product conversion'' program which resulted in 96,000 brand-name conversions. In this scenario, for instance, Drug Company A offered a cash award to pharmacies for each time a drug prescription was changed from Drug Company B's product to Drug Company A's product. The pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription.

- A ``frequent flier'' campaign in which physicians were given credit toward airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on the drug company's product.

- A ``research grant'' program in which physicians were given substantial payments for de minimis recordkeeping tasks. The physician administered the drug manufacturer's product to the patient and made brief notes, sometimes a single word, about the treatment outcome. Upon completion of a limited number of such ``studies,'' the physician received payment from the manufacturer.

If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or ``safe harbor'' to protect such activities. Thus a physician, pharmacy or other practitioner or supplier receiving payment under these activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. The OIG is investigating various drug marketing schemes, and enforcing the anti-kickback laws where these practices affect the

Federal health care programs.

What To Look For

Generally, a payment or gift may be considered improper under 42 U.S.C. 1320a-7b(b) if it is:

- Made to a person in a position to generate business for the paying party;

- Related to the volume of business generated; and

- More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

OIG investigation may be warranted where one or more of the following features is present in prescription drug marketing activities:

- Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.

- Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented ``educational'' or ``counseling'' contacts, or physician and/or patient outreach, etc.

- Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.

- Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with a ``safe harbor'' regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices.

F. Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services
(Issued October 1994)

How Does the Anti-Kickback Statute Relate to Arrangements for the Provision of Clinical Lab Services?

Many physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Since the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician's decision regarding

where to refer specimens is based only on the best interests of the patient.

Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory. By ``fair market value'' we mean value for general commercial purposes. However, ``fair market value'' must reflect an arms length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.

The office of Inspector General has become aware of a number of practices engaged in by clinical laboratories and health care providers that implicate the anti-kickback statute in this manner. Below are some examples of lab services arrangements that may violate the anti-kickback statute.

Provision of Phlebotomy Services to Physicians

When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services.

Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals.

Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [of her] employer or where the contractual prohibition is not rigorously enforced.

Lab Pricing at Renal Dialysis Centers

The Medicare program pays for laboratory tests provided to patients with end stage renal disease (ESRD) in two different ways. Some laboratory testing is considered routine and payment is included in the composite rate paid by Medicare to the ESRD facility which in turn pays the laboratory. Some laboratory testing required by the patient is not included in the composite rate, and these additional tests are billed by the laboratory directly to Medicare and paid at the usual laboratory fee schedule price.

The OIG is aware of cases where a laboratory offers to perform the tests encompassed by the composite rate at a price below fair market value of the tests performed. In order to offset the low charges on the composite rate tests, the ESRD facility agrees to refer all or most of its non-composite rate tests to the laboratory. This arrangement appears to be an offer of something of value (composite rate tests

below fair market value) in return for the ordering of additional tests which are billed directly to the Medicare program.

If offered or accepted in return for referral of additional business, the lab's pricing scheme is illegal remuneration under the anti-kickback statute. The statutory exception and ``safe harbor'' for ``discounts'' does not apply to immunize parties to this type of transaction, since discounts on the composite rate tests are offered to induce referral of other tests. See 42 CFR 1001.952(h)(3)(ii).

Waiver of Charges To Managed Care Patients

Managed care plans may require a physician or other health care provider to use only the laboratory with which the plan has negotiated a fee schedule. In such situations, the plan usually will refuse to pay claims submitted by other laboratories. The provider, however, may use a different laboratory and may wish to continue to use that laboratory for non-managed care patients. In order to retain the provider as a client, the laboratory that does not have the managed care contract may agree to perform the managed care work free of charge.

The status of such agreements under the anti-kickback statute depends in part on the nature of the contractual relationship between the managed care plan and its providers. Under the terms of many managed care contracts, a provider receives a bonus or other payment if utilization of ancillary services, such as laboratory testing, is kept below a particular level. Other managed care plans impose financial penalties if the provider's utilization of services exceeds pre-established levels. When the laboratory agrees to write off charges for the physician's managed care work, the physician may realize a financial benefit from the managed care plan created by the appearance that utilization of tests has been reduced.

In cases where the provision of free services results in a benefit to the provider, the anti-kickback statute is implicated. If offered or accepted in return for the referral of Medicare or State health care plan business, both the laboratory and the physician may be violating the anti-kickback statute. There is no statutory exception or ``safe harbor'' to immunize any party to such a practice because the Federal programs do not realize the benefit of these ``free'' services. See 42 CFR 1001.952(h)(3)(iii).

Other Inducements

The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute:

- Free pick-up and disposal of bio-hazardous waste products (such as sharps) unrelated to the collection of specimens for the outside laboratory.

- Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.

- Provision of free laboratory testing for health care providers, their families and their employees.

When one purpose of these arrangements is to induce the referral of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider may be liable under the statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

G. Reporting Information

What To Do If You Have Information About Suspect Activities or Arrangements

If you have information about health care providers, practitioners, entities or other persons engaging in these types of activities or arrangements described above, contact any of the regional offices of the Office of Investigations of the Office of Inspector General, U.S. Department of Health and Human Services, at the following locations:

Regions	States served	Telephone
Boston.....	MA, VT, NH, ME, RI, CT.....	617-565-2660
New York.....	NY, NJ, PR, VI.....	212-264-1691
Philadelphia.....	PA, MD, DE, WV, VA.....	215-596-6796
Atlanta.....	GA, KY, NC, SC, FL, TN, AL, MS (No. District).	404-331-2131
Chicago.....	IL, MN, WI, MI, IN, OH, IA, MO....	312-353-2740
Dallas.....	TX, NM, OK, AR, LA, MS (So. District).	214-767-8406
Denver.....	CO, UT, WY, MT, ND, SD, NE, KS....	303-844-5621
Los Angeles.....	AZ, NV (Clark Co.), So. CA.....	714-836-2372
San Francisco.....	No. CA, NV, AZ, HI, OR, ID, WA....	415-556-8880
Washington, DC.....	DC and Metropolitan areas of VA and MD.	202-619-1900

Dated: December 2, 1994.
June Gibbs Brown,
Inspector General.
[FR Doc. 94-31157 Filed 12-16-94; 8:45 am]
BILLING CODE 4150-04-P

EXHIBIT E

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Health Officer

EDMUND G. BROWN JR.
Governor

IMPORTANT NOTICE REGARDING NON-COMPLIANCE INDUCEMENTS

Background and regulations:

Business and Professions Code (B&PC) section 650 states in part that the: ***". . .offer, delivery, receipt, or acceptance by any person licensed under this division of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration . . . as . . . compensation or inducement for referring patients . . . to any person . . . is unlawful."***

Violation of the above is punishable by imprisonment, a fine of up to $50,000, or both. This law applies to referrals by physicians, dentists, nurses, and other health professionals, including chiropractors. The intent of the law is to protect the public from excessive health care costs, from referrals based on considerations other than the best interests of the patients, deceit and fraud, and payment to a licensee where professional services have not been rendered.

Possible scenarios:

1. A laboratory places phlebotomy personnel in a physician's office. These personnel are either employed by the laboratory or contracted by the laboratory directly or indirectly through a third party. In this scenario, the phlebotomy services are offered solely to the physician's patients and are not available to the public, and the laboratory may or may not pay fair market value to the physician to lease the space occupied by the phlebotomist.

   This is considered an unlawful inducement, regardless of whether the laboratory is paying fair market value to the physician for the leased space. In exchange for access to phlebotomy services at zero or reduced cost, the physician refers all of the physician's patients to the laboratory; the services are provided solely to the physician's patients and not to the general public. If the laboratory is not paying fair market value to lease the space occupied by the phlebotomist, this is further evidence of an unlawful inducement violation.

2. A laboratory pays an employee of a physician as an "independent" phlebotomist to collect specimens for the physician's patients.

   After the issuance of the federal OIG Special Fraud Alert issued June 25, 2014, a laboratory has changed its practices and now enters into a contractual arrangement directly with an individual, who is a member of a physician's office staff, to provide phlebotomy services to the laboratory. The individual provides the phlebotomy services on-site in the physician's office. The individual remains an employee of the physician's office and simultaneously receives payments directly from the laboratory as an independent contractor to the laboratory. In some circumstances, the physician reduces the salary or compensation to that individual when such an arrangement is in place.

This appears to be an inducement, as the laboratory is conferring a benefit upon the physician by paying a portion of the compensation of the physician's employee. It is an inducement regardless of whether the laboratory is paying fair market value to the physician to lease the space utilized by the phlebotomist.

3. A laboratory places a "roaming phlebotomist" in a physician's office. This phlebotomist is either employed by the laboratory or contracted by the laboratory directly or indirectly through a third party. In this scenario, the phlebotomy services are offered solely to the physician's patients and are not available to the public, and the laboratory may or may not pay fair market value to lease the space occupied by the phlebotomist from the physician. Placement of a "roaming phlebotomist" is the same as placing a laboratory employed or contracted phlebotomist in a physician's office full time.

   This is considered an unlawful inducement, regardless of whether the laboratory is paying fair market value to the physician for the leased space. In exchange for access to phlebotomy services at zero or reduced cost, the physician refers all of the physician's patients to the laboratory; the services provided by the "roaming phlebotomist" are offered solely to the physician's patients and are not available to the general public. If the laboratory is paying fair market value to lease the space occupied by the roaming phlebotomist, this is further evidence of an unlawful inducement violation.

Please note: The responses of LFS contained in this notice are not exhaustive positions on these and similar scenarios.

Laboratory Field Services (LFS) has received complaints of possible violations of BPC section 650. LFS reviewed the complaints and identified approximately 122 facilities for investigation. Between January and August 2017, LFS inspectors investigated these facilities and found five facilities to be out of compliance:

- In four physician offices, phlebotomists placed by a laboratory collected blood only for the physician's patients and did not offer services to the general public.
- In one physician office, a phlebotomist placed by a laboratory stated that the phlebotomy services were available to the public but there was no signage to indicate the availability of the service. In addition, the laboratory was not paying fair market rent to the physician office.

LFS issued statements of deficiencies to these physician offices and all five provided acceptable evidence of correction.

EXHIBIT F

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

Table of Contents
(Rev. 4495, 01-17-20)

10 - Background

(Rev. 1, 10-01-03)
B3-2070, B3-2070.1, B3-4110.3, B3-5114

Diagnostic X-ray, laboratory, and other diagnostic tests, including materials and the services of technicians, are covered under the Medicare program. Some clinical laboratory procedures or tests require Food and Drug Administration (FDA) approval before coverage is provided.

A diagnostic laboratory test is considered a laboratory service for billing purposes, regardless of whether it is performed in:

- A physician's office, by an independent laboratory;
- By a hospital laboratory for its outpatients or nonpatients;
- In a rural health clinic; or
- In an HMO or Health Care Prepayment Plan (HCPP) for a patient who is not a member.

When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory, and still bills the A/B MAC (A). Also, when physicians and laboratories perform the same test, whether manually or with automated equipment, the services are deemed similar.

Laboratory services furnished by an independent laboratory are covered under SMI if the laboratory is an approved Independent Clinical Laboratory. However, as is the case of all diagnostic services, in order to be covered these services must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. A small number of laboratory tests can be covered as a preventive screening service.

See the Medicare Benefit Policy Manual, Chapter 15, for detailed coverage requirements.

See the Medicare Program Integrity Manual, Chapter 10, for laboratory/supplier enrollment guidelines.

See the Medicare State Operations Manual for laboratory/supplier certification requirements.

10.1 - Definitions

(Rev. 85, 02-06-04)
B3-2070.1, B3-2070.1.B, RHC-406.4

"Independent Laboratory" - An independent laboratory is one that is independent both of an attending or consulting physician's office and of a hospital that meets at least the requirements to qualify as an emergency hospital as defined in §1861(e) of the Social Security Act (the Act.) (See the Medicare Benefits Policy Manual, Chapter 15, for detailed discussion.)

"Physician Office Laboratory" - A physician office laboratory is a laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice.

"Clinical Laboratory" - See the Medicare Benefits Policy Manual, Chapter 15.

"Qualified Hospital Laboratory" - A qualified hospital laboratory is one that provides some clinical laboratory tests 24 hours a day, 7 days a week, to serve a hospital's emergency room that is also available to provide services 24 hours a day, 7 days a week. For the qualified hospital laboratory to meet this requirement, the hospital must have physicians physically present or available within 30 minutes through a medical staff call roster to handle emergencies 24 hours a day, 7 days a week; and hospital laboratory technologists must be on duty or on call at all times to provide testing for the emergency room.

"Hospital Outpatient" - See the Medicare Benefit Policy Manual, Chapter 2.

"Referring laboratory" - A Medicare-approved laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.

"Reference laboratory" - A Medicare-enrolled laboratory that receives a specimen from another, referring laboratory for testing and that actually performs the test.

"Billing laboratory" - The laboratory that submits a bill or claim to Medicare.

"Service" - A clinical diagnostic laboratory test. Service and test are synonymous.

"Test" - A clinical diagnostic laboratory service. Service and test are synonymous.

"CLIA" - The Clinical Laboratory Improvement Act and CMS implementing regulations and processes.

"Certification" - A laboratory that has met the standards specified in the CLIA.

"Draw Station' - A place where a specimen is collected but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.

"Medicare-approved laboratory - A laboratory that meets all of the enrollment standards as a Medicare provider including the certification by a CLIA certifying authority.

10.2 - General Explanation of Payment

(Rev. 3510, Issued: 04-29-16, Effective: 10-01-16, Implementation; 10-03-16)

Outpatient laboratory services can be paid in different ways:

- Physician Fee Schedule;
- 101 percent of reasonable cost (critical access hospitals (CAH) only);

  NOTE: When the CAH bills a 14X bill type for a non-patient laboratory specimen, the CAH is paid under the fee schedule.

- Laboratory Fee Schedule;
- Outpatient Prospective Payment System, (OPPS) except for most hospitals in the State of Maryland that are subject to a waiver; or
- Reasonable Charge

Annually, CMS distributes a list of codes and indicates the payment method. Carriers, FIs, and A/B MACs pay as directed by this list. Neither deductible nor coinsurance applies to HCPCS codes paid under the laboratory fee schedule. The majority of outpatient laboratory services are paid under the laboratory fee schedule or the OPPS.

Carriers, FIs and A/B MACs are responsible for applying the correct fee schedule for payment of clinical laboratory tests. FIs/AB MACs must determine which hospitals meet the criteria for payment at the 62 percent fee schedule. Only sole community hospitals with qualified hospital laboratories are eligible for payment under the 62 percent fee schedule. Generally, payment for diagnostic laboratory tests that are not subject to the

clinical laboratory fee schedule is made in accordance with the reasonable charge or physician fee schedule methodologies (or at 101 percent of reasonable cost for CAHs).

For Clinical Diagnostic Laboratory services denied due to frequency edits, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO or PR
CARC: 151
RARC: N/A
MSN: N/A

20 - Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules

(Rev. 4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Section 216 of Public Law 113-93, the "Protecting Access to Medicare Act of 2014," added section 1834A to the Social Security Act (the Act). This provision requires extensive revisions to the payment and coverage methodologies for clinical laboratory tests paid under the clinical laboratory fee schedule (CLFS). The Centers for Medicare & Medicaid Services (CMS) published CMS-1621-F Medicare Clinical Diagnostic Laboratory Tests Payment System, on June 23, 2016, which implemented the provisions of the new legislation.

The final rule set forth new policies for how CMS sets rates for tests on the CLFS and is effective for dates of service on and after January 1, 2018. Beginning on January 1, 2017, applicable laboratories will be required to submit data to CMS which describes negotiated payment rates with private payers for and corresponding volumes of tests on the CLFS. In general, with certain designated exceptions, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payer rates determined for the test, based on data collected from laboratories during a specified data collection period. In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data, reporting, and payment policies associated with them. In particular, the final rule discusses CMS' proposals regarding:

- Definition of "applicable laboratory" (who must report data under section 1834A of the Act)
- Definition of "applicable information" (what data will be reported)
- Data collection period
- Schedule for reporting data to CMS
- Definition of ADLT
- Data Integrity
- Confidentiality and public release of limited data
- Coding for new tests on the CLFS
- Phased in payment reduction

Prior to January 1, 2018

Under Part B, for services rendered on or after July 1, 1984, clinical laboratory tests performed in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients are reimbursed

on the basis of fee schedules. Current exceptions to this rule are CAH laboratory services as described in §10, and services provided by hospitals in the State of Maryland.

Medicare pays the lesser of:

- Actual charges;
- The fee schedule amount for the State or a local geographic area; or
- A national limitation amount (NLA) for the HCPCS code as provided by §1834(h) of the Act.

Annually, CMS furnishes to A/B MACs (A) and (B) the proper amount to pay for each HCPCS code for each local geographic area.

This includes a calculation of whether a national limitation amount or the local fee schedule amount is to be used. This information is available to the public on the CMS Web site in public use files.

20.1 - Initial Development of Laboratory Fee Schedules

(Rev. 4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Initially, each A/B MAC (B) established the fee schedules on an A/B MAC (B)-wide basis (not to exceed a statewide basis). If an A/B MAC (B)'s area includes more than one State, the A/B MAC (B) established a separate fee schedule for each State. The A/B MAC (B) determined the fee schedule amount based on prevailing charges for laboratory billings by physicians and independent laboratories billing the A/B MAC (B). A/B MACs (B) set the fees at 60 percent of prevailing charges. A/B MACs (A) used the same fee schedules to pay outpatient hospital laboratory services. They set the fee at 62 percent of A/B MAC (B) prevailing charges. Subsequently, except for sole community hospitals, which continue to be paid at the 62 percent rate, A/B MACs (A) changed payments to hospital laboratories to the "60 percent fee schedule."

In 1994, CMS took over the annual update and distribution of clinical laboratory fee schedules. The CMS updates the fee schedule amounts annually to reflect changes in the Consumer Price Index (CPI) for all Urban Consumers (U.S. city average), or as otherwise specified by legislation.

Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988, to receive the 62 percent fee the hospital must be a sole community hospital. Otherwise, the fee is the "60 percent fee schedule." If a hospital is uncertain whether it meets the qualifications of a sole community hospital it can seek assistance from the A/B MAC (A) or the RO.

For tests to hospital non-patients, the fee is 60 percent of the A/B MAC (B) prevailing charge. If a hospital laboratory acts as an independent laboratory, i.e., performs tests for persons who are nonhospital patients; or if the hospital laboratory is not a qualified hospital laboratory, the services are reimbursed using the 60 percent fee schedule or the adjusted fee schedule, as appropriate.
See §10.1 for the definition of a hospital outpatient.
See §20.3 for CLFS effective January 1, 2018.

20.2 - Annual Fee Schedule Updates

(Rev. 4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

The CMS adjusts the fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers (CPI-U) (U.S. city average) and the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity, unless alternative updates are specified by legislation. The CMS communicates this information via an annual recurring update notification (RUN). The CMS also determines, publishes for A/B MAC (A) or (B) use, and places on its web site, coding and pricing changes. This information is updated on an annual basis.

See §20.3 for CLFS effective January 1, 2018.

20.3 – Clinical Laboratory Fee Schedule Based on Protecting Access to Medicare Act (PAMA) of 2014

(Rev. 4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Effective January 1, 2018, CLFS rates were based on weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014.

Fee Schedule Through December 31, 2017

Outpatient clinical laboratory services are paid based on a fee schedule in accordance with Section 1833 (h) of the Social Security Act. Payment is lesser of the amount billed, the local fee for a geographic area, or a national limit. In accordance with the statute, the national limits are set at a percent of the median of all local fee schedule amounts for each laboratory test code. Each year, fees are updated for inflation based on the percentage change in the Consumer Price Index. However, legislation by Congress can modify the update to the fees. Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule.

Each year, new laboratory test codes are added to the clinical laboratory fee schedule and corresponding fees are developed in response to a public comment process. Also, for a cervical or vaginal smear test (pap smear), the fee cannot be less than a national minimum payment amount, initially established at $14.60 and updated each year for inflation.

Sole Community Hospitals

Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988 through December 31, 2017, to receive the 62 percent fee the hospital must be a sole community hospital. Effective for hospital outpatient tests furnished by a Sole community possessive hospital's payment is based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is the lesser of the amount billed, the local fee for a geographic area, or a national limit.

Critical Access Hospitals

Critical access hospitals are generally paid for outpatient laboratory tests on a reasonable cost basis, instead of by the fee schedule, as long as the lab service is provided to a CAH outpatient.

30 - Special Payment Considerations

(Rev. 1, 10-01-03)

30.1 - Mandatory Assignment for Laboratory Tests

(Rev. 1, 10-01-03)
B3-5114.1

Unless a laboratory, physician, or medical group accepts assignment, the A/B MAC (B) makes no Part B payment for laboratory tests paid on the laboratory fee schedule. Laboratories, physicians, or medical groups that have entered into a participation agreement must accept assignment. Sanctions of double the violation

charges, civil money penalties (up to $2,000 per violation), and/or exclusion from the program for a period of up to five years may be imposed on physicians and laboratories, with the exception of rural health clinic laboratories, that knowingly, willfully, and repeatedly bill patients on an unassigned basis. However, sole community physicians and physicians who are the sole source of an essential specialty in a community are not excluded from the program. Whenever a A/B MAC (B) is notified of a sanction action for this reason, the A/B MAC (B) does not pay for any laboratory services unless the services were furnished within 15 days after the date on the exclusion or suspension notice to the practitioner, and:

- It is the first claim filed for services rendered to that beneficiary after the date on the notice of suspension or exclusion; or

- It is filed with respect to services furnished within 15 days of the date on the first notice of denial of claims to the beneficiary. (Fifteen days are allowed for the notice to reach the beneficiary.)

A/B MACs (B) refer questions on payment procedures to the Sanctions Coordinator in the RO.

A/B MACs (B) process laboratory claims inadvertently submitted as unassigned as if they were assigned. (See §50.)

For purposes of this section, the term assignment includes assignment in the strict sense of the term as well as the procedure under which payment is made, after the death of the beneficiary, to the person or entity that furnished the service, on the basis of that person's or entity's agreement to accept the Medicare payment as the full charge or fee for the service.

30.1.1 - Rural Health Clinics

(Rev. 1, 10-01-03)
PM A-99-8, Rev. 810, CR 1133, PM A-00-30

Rural Health Clinics (RHCs) must furnish the following laboratory services to be approved as an RHC. However, these and other laboratory services that may be furnished are not included in the encounter rate and must be billed separately:

- Chemical examinations of urine by stick or tablet method or both;
- Hemoglobin or hematocrit;
- Blood sugar;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory (No CPT code available).

Effective January 1, 2001, freestanding RHCs/Federally Qualified Health Centers (FQHCs) bill all laboratory services to the A/B MAC (B), and provider based RHCs/FQHCS bill all laboratory tests to the A/B MAC (A) under the host provider's bill type. In either case payment is made under the fee schedule. HCPCS codes are required for laboratory services. (See §40.4 for details on RHC billing.)

30.2 - Deductible and Coinsurance Application for Laboratory Tests

(Rev. 2581, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Neither the annual cash deductible nor the 20 percent coinsurance apply to:

- Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis;

- Specimen collection fees; or

- Travel allowance related to laboratory tests (e.g., collecting specimen).

Codes on the physician fee schedule are generally subject to the Part B deductible and coinsurance, although exceptions may be noted for a given code in the MPFS or through formal Medicare instructions such as temporary instructions and requirements for specific services noted in this manual.

Any laboratory code paid at reasonable charge is subject to the Part B deductible and coinsurance, unless otherwise specified in the description of coverage and payment rules.

30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

(Rev. 3685, Issued: 12-22-16, Effective: 01-01-17, Implementation: 01-03-17)

The following apply in determining the amount of Part B payment for clinical laboratory tests:

Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule (CLFS) will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Independent laboratory or a physician or medical group - Payment to an independent laboratory or a physician or medical group is the lesser of the actual charge, the fee schedule amount or the national limitation amount. Part B deductible and coinsurance do not apply.

Reference laboratory - For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount, or the national limitation amount (NLA). (See §50.5 for A/B MAC (B) jurisdiction details.) Part B deductible and coinsurance do not apply.

Outpatient of **OPPS** hospital - For hospitals paid under the OPPS, beginning January 1, 2014 outpatient laboratory tests are generally packaged as ancillary services and do not receive separate payment. Only in the following circumstance are lab tests eligible for separate payment under the CLFS.

(1) Outpatient lab tests only - If the hospital only provides outpatient laboratory tests to the patient (directly or under arrangement) and the patient does not also receive other hospital outpatient services on that day.

Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, furnished to an outpatient of the hospital, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Exception: Reasonable cost reimbursement has been provided for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning on July 1, 2004 through 2008 (per the following legislation: Section 416 of the Medicare Modernization Act (MMA) of 2003, Section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006, and Section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007). Section 3122 of the Patient Protection and Affordable Care Act re-institutes the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. Section 109 of the Medicare and Medicaid Extenders Act extends the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2011, through June 30, 2012.

Non-Patient (Referred) Laboratory Specimen- A non-patient is defined as a beneficiary that is neither an inpatient nor an outpatient of a hospital, but that has a specimen that is submitted for analysis to a hospital and the beneficiary is not physically present at the hospital. All hospitals (including Maryland waiver hospitals and CAHs) bill non-patient lab tests on TOB 14X. They are paid under the clinical laboratory fee schedule at the lesser of the actual charge, the fee schedule amount, or the NLA (including CAH and MD Waiver hospitals). Part B deductible and coinsurance do not apply.

Inpatient without Part A – Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS. For hospitals subject to the OPPS, beginning January 1, 2014 Part B inpatient laboratory tests are packaged as ancillary services and do not receive separate payment unless the service with which the labs would otherwise be packaged is not a payable Part B inpatient service (see Chapter 6, Section 10 of the Medicare Benefit Policy Manual, Pub. 100-02). Payment to a SNF inpatient without Part A coverage is made under the laboratory fee schedule.

Inpatient or SNF patient with Part A - Payment to a hospital for laboratory tests furnished to an inpatient, whose stay is covered under Part A, is included in the PPS rate for PPS facilities or is made on a reasonable cost basis for non-PPS hospitals and is made at 101 percent of reasonable cost for CAHs. Payments for lab services for beneficiaries in a Part A stay in a SNF, other than a swing bed in a CAH are included in the SNF PPS rate. For such services provided in a swing bed of a CAH, payment is made at 101 percent of reasonable cost.

Sole community hospital – Sole community hospitals are subject to the OPPS, therefore OPPS packaging rules apply. When the OPPS exception for separate payment of outpatient laboratory tests under the CLFS applies, a sole community hospital with a qualified hospital laboratory identified on the hospital's certification in the Provider Specific File is paid the least of the actual charge, the 62 percent fee schedule amount, or the 62 percent NLA. The Part B deductible and coinsurance do not apply.

Waived Hospitals - Payment for outpatient (bill type13X), to a hospital which has been granted a waiver of Medicare payment principles for outpatient services is subject to Part B deductible and coinsurance unless otherwise waived as part of an approved waiver. Specifically, laboratory fee schedules do not apply to laboratory tests furnished by hospitals in States or areas that have been granted waivers of Medicare reimbursement principles for outpatient services. The State of Maryland has been granted such a waiver. Payment for non-patient laboratory specimens (bill type14X) is based on the fee schedule. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be paid based on current methodology.

Critical Access Hospital - When the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the laboratory fee schedule. If the beneficiary is an outpatient of the CAH, the CAH bills using an 85x bill type and is paid based on 101 percent of reasonable cost.

Beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to CAH clinical laboratory services.

<u>Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA)</u>

Effective for services furnished on or after July 1, 2009, the beneficiary is no longer required to be physically present in a CAH at the time the specimen is collected in order for the CAH to be paid based on 101 percent of reasonable cost. However, the beneficiary must be an outpatient of the CAH, as defined at 42 CFR §410.2 and be receiving services directly from the CAH. In order for the beneficiary to be receiving services directly from the CAH if he/she is not present in the CAH when the specimen is collected, the beneficiary must either be receiving outpatient services in the CAH on the same day the specimen is collected, or the specimen must be collected by an employee of the CAH or of a facility provider-based to the CAH.

Dialysis facility - Effective for items and services furnished on or after January 1, 2011 Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) requires that all ESRD-related laboratory tests be reported by the ESRD facility whether provided directly or under arrangements with an independent laboratory. When laboratory services are billed by a laboratory other than the ESRD facility and the laboratory service furnished is designated as a laboratory test that is included in the ESRD PPS (i.e., ESRD-related), the claim will be rejected or denied. The list of items and services subject to consolidated billing

located at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD. In the event that an ESRD-related laboratory service was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the supplier may submit a claim for separate payment using modifier "AY". See Pub.100-04, Chapter 8 for more information regarding Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims.

Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC) - Payment to a RHC/FQHC for laboratory tests performed for a patient of that clinic/center is not included in the all-inclusive rate and may be billed separately by either the base provider for a provider-based RHC/FQHC, or by the physician for an independent or free-standing RHC/FQHC. Payment for the laboratory service is not subject to Part B deductible and coinsurance. If the RHC/FQHC is provider-based, payment for lab tests is to the base provider (i.e., hospital). If the RHC/FQHC is independent or freestanding, payment for lab tests is made to the practitioner (physician) via the clinical lab fee schedule. (See Sections 30.1.1 and 40.5 for details on RHC/FQHC billing.)

Enrolled in Managed Care - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

Non-enrolled Managed Care - Payment to a participating HMO or HCPP for laboratory tests performed for a patient who is not a member is the lesser of the actual charge, or the fee schedule, or the NLA. The Part B deductible and coinsurance do not apply.

Hospice - Payment to a hospice for laboratory tests performed by the hospice is included in the hospice rate.

30.4 - Payment for Review of Laboratory Test Results by Physician

(Rev. 1, 10-01-03)
B3-5114.2

Reviewing results of laboratory tests, phoning results to patients, filing such results, etc., are Medicare covered services. Payment is included in the physician fee schedule payment for the evaluation and management (E and M) services to the patient. Visit services entail a wide range of components and activities that may vary somewhat from patient to patient. The CPT lists different levels of E and M services for both new and established patients and describes services that are included as E and M services. Such activities include obtaining, reviewing, and analyzing appropriate diagnostic tests.

40 - Billing for Clinical Laboratory Tests

(Rev. 1, 10-01-03)

40.1 - Laboratories Billing for Referred Tests

(Rev. 85, 02-06-04)
B3-5114.1.E,

Section 1833(h)(5)(A) of the Act provides that a referring laboratory may bill for clinical laboratory diagnostic tests on the clinical laboratory fee schedule for Medicare beneficiaries performed by a reference laboratory only if the referring laboratory meets certain conditions. Payment may be made to the referring laboratory but only if one of the following conditions is met:

- the referring laboratory is located in, or is part of, a rural hospital;
- the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity; or

- the referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year (not counting referrals made under the wholly-owned condition described above).

In the case of a clinical laboratory test provided under an arrangement (as defined in §1861(w)(1)) made by a hospital, CAH or SNF, payment is made to the hospital or SNF.

Examples of 30 Percent Exception:

(1) - A laboratory receives requests for 200 tests, performs 139 tests, and refers 61 tests to a non-related laboratory. All tests referred to a non-related laboratory are counted. Thus, 30.5 percent (61/200) of the tests are considered tests referred to a non-related laboratory and, since this exceeds the 30 percent standard, the referring laboratory may not bill for any Medicare beneficiary laboratory tests referred to a non-related laboratory.

(2) - A laboratory receives requests for 200 tests, performs 139 tests and refers 15 to a related laboratory and 46 to a non-related laboratory. Only 23 percent of the tests were referred to non-related laboratories. Since this is less than 30 percent, the referring laboratory may bill for all tests.

If it is later found that a referring laboratory does not, in fact, meet an exception criterion, the A/B MAC (B) should recoup payment for the referred tests improperly billed. The RO shall take whatever action is necessary to correct the problem.

NOTE: This provision of §6111(b) of OBRA of 1989 has no effect on hospitals that are paid under §1833(h)(5)(A)(iii).

NOTE: Laboratory services provided to a SNF inpatient under Part A are billed by the SNF, not the laboratory, due to consolidated billing for SNFs.

Only one laboratory may bill for a referred laboratory service. It is the responsibility of the referring laboratory to ensure that the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so.

40.1.1 - Claims Information and Claims Forms and Formats

(Rev. 85, 02-06-04)

Claims for referred laboratory services may be made only by suppliers having specialty code 69, i.e., independent clinical laboratories. Claims for referred laboratory services made by other entities will be returned as unprocessable.

Independent laboratories shall use modifier 90 to identify all referred laboratory services. A claim for a referred laboratory service that does not contain the modifier 90 is returned as unprocessable if the claim can otherwise be identified as being for a referred service.

The name, address, and CLIA number of both the referring laboratory and the reference laboratory shall be reported on the claim.

40.1.1.1 - Paper Claim Submission to A/B MACs (B)

(Rev. 3255, Issued: 05-08-15, Effective: 10-01-15, Implementation: 10-05-15)

An independent clinical laboratory may file a paper claim form shall file Form CMS-1500 for a referred laboratory service (as it would any laboratory service). The line item services must be submitted with a modifier 90.

An independent clinical laboratory that submits claims in paper format) may not combine non-referred (i.e., self-performed) and referred services on the same CMS 1500 claim form. When the referring laboratory bills for both non-referred and referred tests, it shall submit two separate claims, one claim for non-referred tests, the other for referred tests. If billing for services that have been referred to more than one laboratory, the referring laboratory shall submit a separate claim for each laboratory to which services were referred (unless one or more of the reference laboratories are separately billing Medicare). A paper claim that contains both non-referred and referred tests is returned as unprocessable. When the referring laboratory is the billing laboratory, the reference laboratory's name, address, and ZIP Code shall be reported in item 32 on the CMS-1500 claim form to show where the service (test) was actually performed. The NPI shall be reported in item 32a. Also, the CLIA number of the reference laboratory shall be reported in item 23 on the CMS-1500 claim form. A paper claim that does not have the name, address, and ZIP Code of the reference laboratory in item 32 and NPI in 32a or the CLIA number of the reference laboratory in item 23 is returned as unprocessable.

EXAMPLE: A physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory.

Result: The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory) submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, address, and ZIP Code are also reported in item 32 and the NPI is reported in item 32a on Form CMS-1500 to show where the service (test) was actually rendered.

NOTE: Effective for claims submitted with a receipt date on and after October 1, 2015, the billing physician or supplier must report the name, address, and NPI of the performing physician or supplier in Item 32a on anti-markup and reference laboratory claims, even if the performing physician or supplier is enrolled in a different A/B MAC (B) jurisdiction. See Pub. 100-04, Chapter 1, §10.1.1 for more information regarding claims filing jurisdiction.

40.1.1.2 - Electronic Claim Submission to A/B MACs (B)

(Rev. 3255, Issued: 05-08-15, Effective: 10-01-15, Implementation: 10-05-15)

Electronic Claim Submission

ASC X12 837 professional claim format (HIPAA compliant version):

CLIA number:

An electronic claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim. An electronic claim for laboratory testing must be submitted using the following rules:

Electronic claim: the billing laboratory performs all laboratory testing:

The independent laboratory submits a single claim for CLIA-covered laboratory tests and reports the billing laboratory's number in:

loop 2300, REF02. REF01 = X4

Electronic claim: billing laboratory performs some laboratory testing; some testing is referred to another laboratory:

The claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

The billing laboratory submits, on the same claim, tests referred to another (referral/rendered) laboratory, with modifier 90 reported on the line item and reports the referral laboratory's CLIA number in:

loop 2400, REF02. REF01 = F4

EXAMPLE: A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:

loop 2300, REF02. REF01 = X4

On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:

loop 2400, REF02. REF01 = F4

Reference Laboratory's Address:

An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the appropriate 837 loop.

NOTE: Effective for claims submitted with a receipt date on and after October 1, 2015, the billing physician or supplier must report the name, address, and NPI of the performing physician or supplier on the claim on reference laboratory claims, even if the performing physician or supplier is enrolled in a different A/B MAC(B) jurisdiction. See Pub. 100-04, Chapter 1, §10.1.1 for more information regarding claims filing jurisdiction.

40.2 - Payment Limit for Purchased Services

(Rev. 16, 10-31-03)

For payment instructions for Physician purchased diagnostic tests refer to the Claims Processing Manual 100-04, Chapter 1, §30.2.9, Chapter 13 §20.2.4ff.

When an Independent Laboratory (IL) bills for the technical component (TC) of a physician pathology service purchased from a separate physician or supplier, the payment amount for the TC is based on the lower of the billed charge or the Medicare Physician Fee Schedule. The purchase diagnostic test payment provision does not apply, thus, the purchase service information shall not be entered on the claim.

All purchased diagnostic services are based on the Medicare Physician Fee Schedule and are subject to the jurisdiction rules for that fee schedule.

The IL must perform at least one of the component services. If they purchase both the PC and the TC services, only the physician or supplier that performed those services may bill.

40.3 - Hospital Billing Under Part B

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Hospital laboratories, billing for either outpatient or non-patient claims, bill the A/B MAC (A).

Neither deductible nor coinsurance applies to laboratory tests paid under the fee schedule.

Hospitals must follow requirements for submission of the ASC X12 837 institutional claim or the hardcopy Form CMS-1450. (See Chapter 25 for a description of the data set, and for requirements for the paper form. See the ASC X12 837 implementation guide for billing requirements for the electronic claim,).

When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services.

As discussed in section 30.3 ("Place of Service Variation, Critical Access Hospitals") of this chapter, when the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the clinical laboratory fee schedule. For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost only if the beneficiary is an outpatient of the CAH (85X TOB), as defined in 42 CFR 410.2, and is physically present in the CAH at the time the specimen is collected, for dates of service prior to July 1, 2009. However, for dates of service on or after July 1, 2009, the beneficiary does not have to be physically present in the CAH at the time the specimen is collected as long as certain criteria are met, per Section 148 of the MIPPA (i.e. other outpatient services are received by the beneficiary in the CAH on the same day the specimen is collected, or the specimen is collected by an employee of the CAH or of a facility provider-based to the CAH) (see Section 30.3 above, Critical Access Hospital). Clinical diagnostic laboratory tests performed for a beneficiary who is not physically present at the CAH when the specimen is collected, by a non-CAH employee or who are not receiving other outpatient services in the CAH on the same day the specimen is collected, are paid are paid for under the clinical lab fee schedule. Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule.

Section 416 of the Medicare Prescription, Drug, Improvement, and Modernization Act (MMA) of 2003 also eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital laboratory with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the 2-year period beginning on July 1, 2004. Payment for these hospital outpatient laboratory tests will be reasonable costs without coinsurance and deductibles during the applicable time period. A qualified rural area is one with a population density in the lowest quartile of all rural county populations.

The reasonable costs are determined using the ratio of costs to charges for the laboratory cost center multiplied by the PS&R's billed charges for outpatient laboratory services for cost reporting periods beginning on or after July 1, 2004 but before July 1, 2006.

In determining whether clinical laboratory services are furnished as part of outpatient services of a hospital, the same rules that are used to determine whether clinical laboratory services are furnished as an outpatient critical access hospital service will apply.

40.3.1 - Critical Access Hospital (CAH) Outpatient Laboratory Service

(Rev. 2971, Issued: 05-23-14, Effective: 07-01-14, Implementation: 07-07-14)

Effective for services furnished on or after the enactment of the Balanced Budget Refinement Act of 1999 (BBRA), Medicare beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to clinical laboratory services furnished as a CAH outpatient service. This change is effective for claims with dates of service on or after November 29, 1999.

For CAH bill type 85X, the laboratory fees are paid at 101 percent of reasonable cost. When the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the clinical laboratory fee schedule.

40.4 - Special Skilled Nursing Facility (SNF) Billing Exceptions for Laboratory Tests

(Rev. 1, 10-01-03)
SNF 541, A3-3137.1, HO-437, B3-5114.1

When a SNF furnishes laboratory services directly, it must have a Clinical Laboratory Improvement Act (CLIA) number or a CLIA certificate of waiver, and the laboratory itself must be in the portion of the facility so certified. Normally the A/B MAC (A) makes payment under Part B for clinical laboratory tests only to the entity that performed the test. However, the law permits SNFs to submit a Part B claim to the A/B MAC (A) for laboratory tests that it makes arrangements for another entity to perform on the SNF's behalf. Section 1833(h)(5) of the Act (as enacted by The Deficit Reduction Act of 1984, P.L. 98-369) requires the establishment of a fee schedule for clinical laboratory tests paid under Part B and also requires that, with certain exceptions, only the entity that performed the test may be paid.

The fee schedule applies to all SNF clinical laboratory services.

Where a SNF operates a laboratory that provides laboratory services to patients other than its own patients, it is functioning as a clinical laboratory. The billing for these laboratory services depends upon the HCPCS code as defined in the CMS annual fee schedule releases (laboratory and MPFS), and the arrangements made for payment with the referring entity (e.g., does the SNF or the referring entity bill under the agreement between the two). The SNF is responsible for ascertaining the necessary information for billing the A/B MAC (A). Any questions must be referred to the A/B MAC (A).

40.4.1 - Which A/B MAC (A) or (B) to Bill for Laboratory Services Furnished to a Medicare Beneficiary in a Skilled Nursing Facility (SNF)

(Rev. 1, 10-01-03)

Inpatient Part A beneficiary - SNF bills the A/B MAC (A) under Part A. The service is included in SNF PPS payment.

Inpatient Part B beneficiary (benefits exhausted or no Part A entitlement) - SNFs may provide the service and bill the A/B MAC (A), may obtain the service under arrangement and bill the A/B MAC (A) under Part B, or may have agreement with a reference laboratory for the reference laboratory to provide the service and have the reference laboratory bill the A/B MAC (B) under Part B. Regardless of who bills, CMS policy requires that the service be paid under the fee schedule, whether or not the beneficiary is in a Medicare certified bed.

Outpatient Part B - See inpatient Part B beneficiary (benefits exhausted or no Part A entitlement), immediately above.

40.5 - Rural Health Clinic (RHC) Billing

(Rev. 1, 10-01-03)
B3-3628

For independent RHCs, laboratory services provided in the RHC's laboratory are not included in the all-inclusive rate payment to the RHC and may be billed separately to the A/B MAC (B). This includes the six basic laboratory tests required for certification as well as any other laboratory tests provided in the RHC laboratory.

Note: If the RHC sends laboratory services to an outside laboratory, the outside laboratory bills the A/B MAC (B) for the tests.

If the RHC laboratory becomes certified as a clinical laboratory, it bills all laboratory tests performed in its laboratory to the laboratory's A/B MAC (B). Laboratory tests are not included as RHC costs nor as part of the RHC all-inclusive rate payment.

For provider based RHCs the rules in the preceding paragraph apply with the following exception. The provider bills tests provided in its laboratory to the A/B MAC (A).

40.6 - Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests

(Rev. 2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate and must be reported by the ESRD facility and are not separately paid. For instructions on ESRD facility billing under ESRD PPS, see Publication 100-04, Chapter 8. The list of items and services subject to consolidated billing located at http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD.

Laboratory services that are not related to the treatment of ESRD are separately billable under the ESRD PPS and may be billed by either the ESRD facility or the independent laboratory. If the ESRD facility or independent laboratory bills a laboratory service that was not related to the treatment of ESRD, the bill must include the modifier AY. The AY modifier serves as an attestation that the item or service is medically necessary for the dialysis patient but is not being used for the treatment of ESRD.

40.6.1 - Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries

Rev. 3116, Issued: 11-06-14, Effective: 04-01-15, Implementation: 04-06-15)

Instructions for Services Provided on and After January 1, 2011

Section 153b of the MIPPA requires that all ESRD-related laboratory tests must be reported by the ESRD facility whether provided directly or under arrangements with an independent laboratory. When laboratory services are billed by providers other than the ESRD facility and the laboratory test furnished is designated as a laboratory test that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related laboratory test was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY. The AY modifier serves as an attestation that the item or service is medically necessary for the dialysis patient but is not being used for the treatment of ESRD. The items and services subject to consolidated billing located on the CMS website includes the list of ESRD-related laboratory tests that are routinely performed for the treatment of ESRD.

For services provided on or after January 1, 2011, the 50/50 rule no longer applies to independent laboratory claims for AMCC tests furnished to ESRD beneficiaries. The 50/50 rule modifiers (CD, CE, and CF) are no longer required for independent laboratories effective for dates of service on and after January 1, 2011. However, for services provided between January 1, 2011 and March 31, 2015, the 50/50 rule modifiers are still required for use by ESRD facilities that are receiving the transitional blended payment amount (the transition ends in CY 2014). For services provided on or after April 1, 2015, the 50/50 rule modifiers are no longer required for use by ESRD facilities.

Effective for dates of service on and after January 1, 2012, A/B MACs (B) shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by independent laboratories for AMCC panel tests furnished to ESRD eligible beneficiaries if:

- The beneficiary is not receiving dialysis treatment for any reason (e.g., post-transplant beneficiaries), or

- The test is not related to the treatment of ESRD, in which case the supplier would append modifier "AY".

A/B MACs (B) shall make payment for organ disease panels according to the Clinical Laboratory Fee Schedule and shall apply the normal ESRD PPS editing rules for independent laboratory claims. The aforementioned organ disease panel codes were added to the list of bundled ESRD PPS laboratory tests in January 2012.

Effective for dates of service on and after April 1, 2015, A/B MACs (A) shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by ESRD facilities for AMCC panel tests furnished to ESRD eligible beneficiaries if:

- These codes best describe the laboratory services provided to the beneficiary, which are paid under the ESRD PPS, or

- The test is not related to the treatment of ESRD, in which case the ESRD facility would append modifier "AY" and the service may be paid separately from the ESRD PPS.

Instructions for Services Provided Prior to January 1, 2011

For claims with dates of service prior to January 1, 2011, Medicare will apply the following rules to Automated Multi-Channel Chemistry (AMCC) tests for ESRD beneficiaries:

- Payment is at the lowest rate for tests performed by the same provider, for the same beneficiary, for the same date of service.

- The facility/laboratory must identify, for a particular date of service, the AMCC tests ordered that are included in the composite rate and those that are not included. See Publication 100-02, Chapter 11, Section 30.2.2 for the chart detailing the composite rate tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration as well as a second chart detailing the composite rate tests for Continuous Ambulatory Peritoneal Dialysis (CAPD).

- If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment. In this case, no separate payment in addition to the composite rate is made for any of the separately billable tests.

- If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for that Date of Service (DOS) for that beneficiary are separately payable.

- A noncomposite rate test is defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.

- For A/B MAC (B) processed claims, all chemistries ordered for beneficiaries with chronic dialysis for ESRD must be billed individually and must be rejected when billed as a panel.

(See §100.6 for details regarding pricing modifiers.)

Implementation of this Policy:

ESRD facilities when ordering an ESRD-related AMCC must specify for each test within the AMCC whether the test:

a. Is part of the composite rate and not separately payable;

b. Is a composite rate test but is, on the date of the order, beyond the frequency covered under the composite rate and thus separately payable; or

c. Is not part of the ESRD composite rate and thus separately payable.

Laboratories must:

a. Identify which tests, if any, are not included within the ESRD facility composite rate payment

b. Identify which tests ordered for chronic dialysis for ESRD as follows:

1) Modifier CD: AMCC Test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable.

2) Modifier CE: AMCC Test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity.

3) Modifier CF: AMCC Test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable.

c. Bill all tests ordered for a chronic dialysis ESRD beneficiary individually and not as a panel.

The shared system must calculate the number of AMCC tests provided for any given date of service. Sum all AMCC tests with a CD modifier and divide the sum of all tests with a CD, CE, and CF modifier for the same beneficiary and provider for any given date of service.

If the result of the calculation for a date of service is 50 percent or greater, do not pay for the tests.

If the result of the calculation for a date of service is less than 50 percent, pay for all of the tests.

For A/B MAC (A) processed claims, all tests for a date of service must be billed on the monthly ESRD bill. Providers that submit claims to an A/B MAC (A) must send in an adjustment if they identify additional tests that have not been billed.

A/B MAC (B) shared systems shall adjust the previous claim when the incoming claim for a date of service is compared to a claim on history and the action is adjust payment. A/B MAC (B) shared systems shall spread the payment amount over each line item on both claims (the claim on history and the incoming claim).

The organ and disease oriented panels (80048, 80051, 80053, and 80076) are subject to the 50 percent rule. However, clinical diagnostic laboratories shall not bill these services as panels, they must be billed individually. Laboratory tests that are not covered under the composite rate and that are furnished to CAPD end stage renal disease (ESRD) patients dialyzing at home are billed in the same way as any other test furnished home patients.

A/B MAC (A) Business Requirements for ESRD Reimbursement of AMCC Tests:

Requirement Number	Requirement	Responsibility
1.1	The A/B MAC (A) shared system must RTP a claim for AMCC tests when a claim for that date of service has already been submitted.	Shared system
1.2	Based upon the presence of the CD, CE and CF payment modifiers, identify the AMCC tests ordered that are included and not included in the composite rate payment.	Shared System
1.3	Based upon the determination of requirement 1.2, if 50 percent or more of the covered tests are included under the composite rate, no separate payment is made.	Shared System
1.4	Based upon the determination of requirement 1.2, if less than 50 percent are covered tests included under the composite rate, all AMCC tests for that date of service are payable.	Shared System
1.5	Effective for claims with dates of service on or after January 1, 2006, include any line items with a modifier 91 used in conjunction with the "CD," "CE," or "CF" modifier in the calculation of the 50/50 rule.	Shared System
1.6	A/B MACs (A) must return any claims for additional tests for any date of service within the billing period when the provider has already submitted a claim. Instruct the provider to adjust the first claim.	A/B MAC (A) or Shared System
1.7	After the calculation of the 50/50 rule, services used to determine the payment amount may never exceed 22. Effective for claims with dates of service on or after January 1, 2006, accept all valid line items submitted for the date of service and pay a maximum of the ATP 22 rate.	Shared System

A/B MAC (B) Business Requirements for ESRD Reimbursement of AMCC Tests:

Requirement Number	Requirement	Responsibility
1	The shared systems shall calculate payment at the lowest rate for these automated tests even if reported on separate claims for services performed by the same provider, for the same beneficiary, for the same date of service.	Shared Systems
2	Shared Systems shall identify the AMCC tests ordered that are included and are not included in the composite rate payment based upon the presence of the "CD," "CE" and "CF" modifiers.	Shared Systems
3	Based upon the determination of requirement 2 if 50 percent or more of the covered services are included under the composite rate payment, Shared Systems shall indicate that no separate payment is provided for the services submitted for that date of service.	Shared Systems
4	Based upon the determination of requirement 2 if less than 50 percent are covered services included under the composite rate, Shared Systems shall indicate that all AMCC tests for that date of service are payable under the 50/50 rule.	Shared Systems

Requirement Number	Requirement	Responsibility
5	Effective for claims with dates of service on or after January 1, 2006, include any line items with a modifier 91 used in conjunction with the "CD," "CE," or "CF" modifier in the calculation of the 50/50 rule.	Shared Systems
6	Shared Systems shall adjust the previous claim when the incoming claim is compared to the claim on history and the action is to deny the previous claim. Spread the payment amount over each line item on both claims (the adjusted claim and the incoming claim).	Shared Systems
7	Shared Systems shall spread the adjustment across the incoming claim unless the adjusted amount would exceed the submitted amount of the services on the claim.	Shared System
8	After the calculation of the 50/50 rule, services used to determine the payment amount may never exceed 22. Accept all valid line items for the date of service and pay a maximum of the ATP 22 rate.	Shared Systems

Examples of the Application of the 50/50 Rule

The following examples are to illustrate how claims should be paid. The percentages in the action section represent the number of composite rate tests over the total tests. If this percentage is 50 percent or greater, no payment should be made for the claim.

Example 1: Provider Name: Jones Hospital
DOS 2/1/02, Claim/Services:

CPT Code-	Modifier
82040	Mod CD
82310	Mod CD
82374	Mod CD
82435	Mod CD
82947	Mod CF
84295	Mod CF
82040	Mod CD (Returned as duplicate)
84075	Mod CE
82310	Mod CE
84155	Mod CE

ACTION: 9 services total, 2 non-composite rate tests, 3 composite rate tests beyond the frequency, 4 composite rate tests; 4/9 = 44.4%<50% pay at ATP 09

Example 2: Provider Name: Bon Secours Renal Facility
DOS 2/15/02, Claim/Services:

CPT Code	Modifier
82040	Mod CE and Mod 91
84450	Mod CE
82310	Mod CE
82247	Mod CF
82465	No modifier present

CPT Code	Modifier
82565	Mod CE
84550	Mod CF
82040	Mod CD
84075	Mod CE
82435	Mod CE
82550	Mod CF
82947	Mod CF
82977	Mod CF

ACTION: 12 services total, 5 non-composite rate tests, 6 composite rate tests beyond the frequency, 1 composite rate test; 1/12 = 8.3%<50% pay at ATP 12

Example 3: Provider Name: Sinai Hospital Renal Facility
DOS 4/02/02, Claim/Services:

CPT Code	Modifier
82565	Mod CD
83615	Mod CD
82247	Mod CF
82248	Mod CF
82040	Mod CD
84450	Mod CD
82565	Mod CE
84550	Mod CF
82248	Mod CF (Duplicate

ACTION: 8 services total, 3 non-composite rate tests, 4 composite rate tests, 1 composite rate test beyond the frequency; 4/8 = 50%, therefore no payment is made.

Example 4: Provider Name: Dr. Andrew Ross
DOS 6/01/02, Claim/Services:

CPT Code	Modifier
84460	Mod CF
82247	Mod CF
82248	Mod CF
82040	Mod CD
84075	Mod CD
84450	Mod CD

ACTION: 6 services total, 3 non-composite rate tests and 3 composite rate tests; 3/6 = 50%, therefore no payment.

Example 5: (A/B MAC (B) Processing Example Only)
Payment for first claim, second claim creates a no payment status for either claim.
Provider Name: Dr. Andrew Ross
DOS 6/01/06, Claim/Services - First claim

CPT Code	Modifier
84460	Mod CF
82247	Mod CF
82248	Mod CF

ACTION: 3 services total, 3 non-composite rate tests, 0 composite rate tests beyond the frequency, and 0 composite rate tests, 0/3 = 0%, therefore ATP 03

Example 5: continued (A/B MAC (B) Processing Example Only)
Provider Name: Dr. Andrew Ross

DOS 6/01/06, Claim/Services - Second claim

CPT Code	Modifier
82040	Mod CD
84075	Mod CD
84450	Mod CD

ACTION: An additional 3 services are billed, 0 non-composite rate tests, 8 composite rate tests beyond the frequency, 3 composite rate tests. For both claims there are 6 services total, 3 non-composite rate tests and 3 composite rate tests; 3/6 = 50% ≥ 50%, therefore no payment. An overpayment should be recovered for the ATP 03 payment on the first claim.

40.6.2 - Claims Processing for Separately Billable Tests for ESRD Beneficiaries

(Rev. 1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. If a test profile is performed see §40.6.1. If a clinical laboratory test is performed individually, see §40.6.2.1**.** However the tests are performed in the laboratory setting, the services must be billed individually, and must not be billed in a group as an organ or disease panel.

40.6.2.1 - Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities

(Rev. 3425, Issued: 12-18-15, Effective: 01-01-16, Implementation: 01-04-16)

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. (See §40.3 for details on Part B hospital billing rules for laboratory services.)

Hospital-based laboratories providing separately billable laboratory services to dialysis patients of the hospital's dialysis facility or any other dialysis facility bill and are paid in accordance with the hospital outpatient laboratory provisions in Chapter 16, section 40.3.

40.6.2.2 - Reserved

(Rev. 1655, Issued: 12-31-08, Effective: 01-01-09, Implementation: 02-02-09)

40.6.2.3 - Skilled Nursing Facility (SNF) Consolidated Billing (CB) Editing and Separately Billed ESRD Laboratory Test Furnished to Patients of Renal Dialysis Facilities

(Rev. 4227, Issued: 02-01-2019, Effective: 07-01-19, Implementation: 07-01-19)

Effective April 1, 2003, for dates of service (DOS) on or after April 1, 2001 and ending June 30, 2019:

Effective April 1, 2003, for DOS on or after April 1, 2001, CWF will not apply the SNF CB edits to line items that contain the CB modifier. A provider or supplier may use the "CB" modifier only when it has determined that: (a) the beneficiary has ESRD entitlement, (b) the test is related to the dialysis treatment for ESRD, (c) the test is ordered by a doctor providing care to patients in the dialysis facility, and (d) the test is not included in the dialysis facility's composite rate payment.

Those diagnostic tests that are presumptively considered to be dialysis-related and, therefore, appropriate for submission with the "CB" modifier are identified in Exhibit 1. This list was not designed as an all- inclusive list of Medicare covered diagnostic services. Additional diagnostic services related to the beneficiary's ESRD treatment/care may be considered dialysis-related. However, if these services are not included in our listing, the A/B MAC (A) may require supporting medical documentation.

When a hospital laboratory is billing for laboratory services ordered by an ESRD facility and the patient (beneficiary) is a SNF resident under a Part A stay, the hospital laboratory must use the "CB" modifier for those services excluded from consolidated billing.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic test that are not directly related to the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

Effective for DOS on or after July 1, 2019:

Effective for claims with DOS on or after July 1, 2019, the CB modifier, previously used by Independent Labs when billing for separate payment outside the SNF Consolidated Billing for ESRD dialysis-related lab services, is no longer applicable.

With the January 1, 2011 implementation of the ESRD PPS and effective for DOS on or after July 1, 2019, Exhibit 1 is no longer recognized as the list of separately billable ESRD dialysis-related services. Instead, a list of the recognized renal dialysis laboratory tests that are subject to Part B ESRD PPS consolidated billing requirements, are considered routinely performed for the treatment of ESRD, and are not separately paid when provided to ESRD beneficiaries by providers or suppliers other than the ESRD facility, is located on the CMS Website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

The list of renal dialysis laboratory tests provided in the Part B ESRD PPS consolidated billing requirements is not an all-inclusive list. For laboratory tests not included in this list, the distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD beneficiary's ordering practitioner. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS, is the responsibility of the ESRD facility and is excluded from the SNF PPS. More information regarding renal dialysis services payable under the ESRD PPS is available in Pub. 100-02, chapter 11.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic tests that are not directly related to the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to consolidated billing edits for reasons other than for the treatment of ESRD. When this occurs, the SNF CB applies.

40.7 - Billing for Noncovered Clinical Laboratory Tests

(Rev. 1, 10-01-03)
B3-5114.1

Ordinarily, neither a physician nor a laboratory bills the Medicare Program for noncovered tests. However, if the beneficiary (or his/her representative) contends that a clinical laboratory test which a physician or laboratory believes is noncovered may be covered, the physician or laboratory must file a claim that includes

the test to effectuate the beneficiary's right to a Medicare determination. The physician or laboratory annotates the claim that he/she believes that the test is noncovered and is submitting it at the beneficiary's insistence. Before furnishing a beneficiary a test which the physician or laboratory believes is excluded from coverage as not reasonable and necessary (rather than excluded from coverage as part of a routine physical check-up), the physician or laboratory must obtain a signed Advanced Beneficiary Notice (ABN) from the beneficiary (or representative) that the physician or laboratory has informed him/her of the noncoverage of the test and that there will be a charge for the test. This protects the physician or laboratory against possible liability for the test under the limitation of liability provision.

See Chapter 30, regarding Advance Beneficiary Notices (ABN) and demand bills.

40.8 - Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

(Rev. 4481; Issued: 12-20-19, Effective: 01-01-20, Implementation: 01-23-20)

The DOS policy for either a clinical laboratory test or the technical component of physician pathology service is as follows:

General Rule: The DOS of the test/service must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

Exceptions: The following three exceptions apply to the DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a "chemotherapy sensitivity test" is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare Administrative Contractors (MACs).

C. DOS for Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests:

In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

For the purpose of section 40.8.C, a "blood bank or center" means an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

50 - A/B MAC (B) Claims Processing

(Rev. 1, 10-01-03)

50.1 - Referring Laboratories
(Rev. 85, 02-06-04)
B3-5114.1

Medicare recognizes that specimens drawn or collected by one laboratory are sometimes referred to another laboratory for testing. Payment for a Medicare-covered, referred laboratory service may be made under the rules established in Chapter 15 §40.1.

The rules specified Chapter 15 §40.1 do not apply to services performed in a physician office laboratory or a qualified hospital laboratory. Both circumstances are entirely outside the scope of all sections concerning referral laboratory services.

Every A/B MAC (B) shall process a claim for a referred laboratory service if submitted by an independent clinical laboratory with a physical presence within the A/B MAC (B)'s jurisdiction, notwithstanding that the referred laboratory service may have been performed outside of its jurisdiction.

Every A/B MAC (B) shall maintain the clinical laboratory fee schedules for each A/B MAC (B) jurisdiction and be able to process claims using those fee schedules.

Every A/B MAC (B) shall base payment for a referred service on the fee schedule for the jurisdiction in which the service was performed, i.e., where the test was performed. An exception to this rule allows a payment for a service that is A/B MAC (B)-priced to be based upon the price developed by the A/B MAC (B) processing the claim.

Every A/B MAC (B) that has previously assigned "reference use only" PINs to out-of-jurisdiction laboratories for the purpose of their billing referred services shall cancel such "reference-use-only" PINs.

A/B MACs (B) must use the numerical locality codes specified in 50.4 to identify the appropriate clinical diagnostic laboratory fee schedule for use in pricing a referred laboratory service.

50.2 - Physicians
(Rev. 1, 10-01-03)
B3-4110.2

If a physician or medical group furnishes laboratory tests in an office setting and it is appropriate for them to be performed in the physician's office, no further development of the source of the laboratory tests is required.

If a claim or physician's bill raises a question as to the source of a laboratory test and it cannot be resolved from available information, A/B MACs (B) must request the source of the laboratory service from the physician.

If the clinical laboratory test is subject to the laboratory fee schedule, A/B MACs (B) must pay only the person or entity that performed or supervised the performance of the

test. However, A/B MACs (B) may also pay one physician for tests performed or supervised by another physician with whom he/she shares a practice, i.e., the two physicians are members of a medical group whose physicians submit claims in their own names rather than in the name of the group. Where the medical group submits claims in the name of the group for the services of the physician who performed or supervised the performance of these tests, A/B MACs (B) must pay the group. Regardless of who submits the claim, assignment is required for payment. See §50.2.1 below.

50.2.1 - Assignment Required

(Rev. 3510, Issued: 04-29-16, Effective: 10-01-16, Implementation; 10-03-16)

Carriers must:

- Pay for clinical laboratory services provided in the physician's office only on an assignment basis.

- Treat as assigned any claims for clinical laboratory services provided in the physician's office even if the claimant submits the claim on a non-assigned basis or if the assignment option is not designated.

- Deny claims where it is apparent from the claims form or from other evidence that the beneficiary or provider refuses to assign.

The contractor shall use the following remittance advice message and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO or PR
CARC: 111
RARC: N/A
MSN: 16.41 OR 16.6

50.3 - Hospitals

(Rev. 1, 10-01-03)

50.3.1 - Hospital-Leased Laboratories

(Rev. 1, 10-01-03)
B3-4110.1

A/B MACs (B) process claims from hospital laboratories that are leased by physicians and independent laboratories.

Before processing claims for services furnished by a hospital laboratory department operated on a lease or concession basis by a pathologist or by a nonphysician specialist such as a biochemist (with a visiting pathologist or outside independent laboratory doing the hospital's tissue work), A/B MACs (B) must ascertain if the laboratory has been approved by the RO.

Services furnished by a laboratory that does not meet the hospital laboratory conditions of participation and is operated under a lease arrangement in a domestic emergency hospital are covered only if they are emergency inpatient services payable under Part A.

Additional information concerning nonparticipating emergency hospital services is found in Chapter 3.

50.3.2 - Hospital Laboratory Services Furnished to Nonhospital Patients

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

When a hospital laboratory performs a laboratory service for a non-hospital patient, (i.e., for neither an inpatient nor an outpatient), the hospital bills its A/B MAC (A) on the ASC X12 837 institutional claim format or on the hard copy Form CMS-1450. If an A/B MAC (B) receives such claims, the A/B MAC (B) should deny them. When the lab services are provided in Maryland, services to a hospital's own outpatients are paid under the State cost containment system. A Maryland hospital cannot seek payment based on a percent of charges for tests provided to individuals in locations such as a rural health clinic (RHC), a provider-based HHA, the individual's home or a physician's office). Individuals in these locations are non-patients of the Maryland hospital and their lab tests would be categorized as "non-patient specimen only lab tests" (TOB 14x), and **are** paid under the lab fee schedule.

When a hospital-leased laboratory performs a service for a non-hospital patient, it must bill the A/B MAC (B).

50.4 - Reporting of Pricing Localities for Clinical Laboratory Services

(Rev. 3875, Issued: 10-06-17, Effective: 01-08-18, Implementation: 01-08-18) PM-B-97-12

A/B MACs (B) shall report to the common working file (CWF) new State pricing localities (positions 58 and 59 on the A/B MAC (B) record) indicated on the Clinical Diagnostic Laboratory fee schedule for any reference laboratory service billed with a HCPCS 90 modifier. If the laboratory test billed is not a reference laboratory service, the A/B MAC (B) Locality (location 11-12) on the Clinical Diagnostic Laboratory fee schedule should be forwarded to the CWF. For dates of service on or after April 1, 2004, CWF will not edit clinical laboratory pricing locality.

The A/B MAC (A) and (B) record layouts, plus the State pricing locations are as follows:

A/B MAC (B) RECORD LAYOUT FOR DATA FILE
CLINICAL LABORATORY FEE SCHEDULE

Data Element Name	Picture	Location	Comment
HCPCS Code	X(05)	1-5	

Data Element Name	Picture	Location	Comment
A/B MAC (B) Number	X(05)	6-10	
A/B MAC (B) L	X(02)	11-12	00--Single State A/B MAC (B) 01--North Dakota 02--South Dakota 02--South Dakota 20--Puerto Rico
60% Local Fee	9(05)V99	13-19	
62% Local Fee	9(05)V99	20-26	
60% Natl Limit Amt	9(05)V99	27-33	
62% Natl Limit Amt	9(05)V99	34-40	
60% Pricing Amt	9(05)V99	41-47	
62% Pricing Amt	9(05)V99	48-54	
Gap-Fill Indicator	X(01)	55-55	0 No Gap-fill Required 1-- A/B MAC (B) Gap-fill 2--Special Instructions Apply
Modifier	X(02)	56-57	Where modifier is shown, QW denotes a CLIA waiver test
State Locality	X(02)	58-59	See attached
FILLER	X(01)	60	

A/B MAC (A) RECORD LAYOUT FOR DATA FILE
CLINICAL LABORATORY FEE SCHEDULE

Data Element Name	Picture	Location	Comment
HCPCS	X(05)	1-5	
Filler	X(04)	6-9	
60% Pricing Amt	9(05)V99	10-16	
62% Pricing Amt	9(05)V99	17-23	
Filler	X(07)	24-30	
A/B MAC (B) Number	X(05)	31-35	

Data Element Name	Picture	Location	Comment
A/B MAC (B) Locality	X(02)	36-37	00--Single State A/B MAC (B) 01--North Dakota 02--South Dakota 20 Puerto Rico
State Locality	X(02)	38-39	See Attached
FILLER	X(21)	40-60	

On or after January 1, 2018, the record layouts of the CLFS are as follows:

Data Element Name	Picture	Location	Comment
Year	PIC X(04)	1-4	Calendar year (YYYY) associated with the Clinical Lab Fee Schedule.
Filler	PIC X(01)	5	Value ' '
HCPCS Code	PIC X(05)	6-10	All current year active CPT and alpha-numeric codes subject to CLFS.
Filler	PIC X(01)	11	Value ' '
Modifier	PIC X(02)	12-13	Where modifier is shown, QW denotes a CLIA waiver test.
Filler	PIC X(01)	14	Value ' '
Effective Date	PIC X(08)	15-22	Date the Clinical Lab Fee Schedule became effective (YYYYMMDD).
Filler	PIC X(01)	23	Value ' '
Indicator	PIC X(01)	24	National (N) or Local (L) payment indicator.
Filler	PIC X(01)	25	Value ' '
Payment Rate	PIC Z9(05)V99	26-32	The payment amount associated with each test on the Clinical Lab Fee Schedule.
Filler	PIC X(01)	33	Value ' '
Description	PIC X(40)	34-73	Short description of the applicable HCPCS code.

CarrierLocality/StateLocality Map

Carrier/Loc 1010200 =State Loc 01 (ALABAMA)
Carrier/Loc 0210201 =State Loc 02 (ALASKA)

Carrier/Loc 0310200 =State Loc 04 (ARIZONA)
Carrier/Loc 0710213 =State Loc 05 (ARKANSAS)
Carrier/Loc 0118218 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118226 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111252 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111207 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111205 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111206 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111209 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111251 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111253 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111254 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111255 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111256 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111257 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111258 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111259 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111260 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111261 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111262 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111263 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111264 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111265 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111266 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111267 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111268 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111269 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111270 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118271 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118272 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118273 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118274 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0118217 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0111275 =State Loc 06 (CALIFORNIA)
Carrier/Loc 0411201 =State Loc 08 (COLORADO)
Carrier/Loc 1310200 =State Loc 09 (CONNECTICUT)
Carrier/Loc 1210201 =State Loc 10 (DELAWARE)
Carrier/Loc 1220201 =State Loc 11 (DISTRICT OF COLUMBIA)
Carrier/Loc 0910203 =State Loc 12 (FLORIDA)
Carrier/Loc 0910204 =State Loc 12 (FLORIDA)
Carrier/Loc 0910299 =State Loc 12 (FLORIDA)
Carrier/Loc 1020201 =State Loc 13 (GEORGIA)
Carrier/Loc 1020299 =State Loc 13 (GEORGIA)
Carrier/Loc 0121201 =State Loc 15 (HAWAII/GUAM)
Carrier/Loc 0220200 =State Loc 16 (IDAHO)
Carrier/Loc 0610216 =State Loc 17 (ILLINOIS)
Carrier/Loc 0610212 =State Loc 17 (ILLINOIS)
Carrier/Loc 0610215 =State Loc 17 (ILLINOIS)
Carrier/Loc 0610299 =State Loc 17 (ILLINOIS)

Carrier/Loc 0810200 =State Loc 18 (INDIANA)
Carrier/Loc 0510200 =State Loc 19 (IOWA)
Carrier/Loc 0520200 =State Loc 20 (KANSAS)
Carrier/Loc 1510200 =State Loc 21 (KENTUCKY)
Carrier/Loc 0720201 =State Loc 22 (LOUISIANA)
Carrier/Loc 0720299 =State Loc 22 (LOUISIANA)
Carrier/Loc 1411203 =State Loc 23 (MAINE)
Carrier/Loc 1411299 =State Loc 23 (MAINE)
Carrier/Loc 1230201 =State Loc 24 (MARYLAND)
Carrier/Loc 1230299 =State Loc 24 (MARYLAND)
Carrier/Loc 1421201 =State Loc 25 (MASSACHUSETTS)
Carrier/Loc 1421299 =State Loc 25 (MASSACHUSETTS)
Carrier/Loc 0820201 =State Loc 26 (MICHIGAN)
Carrier/Loc 0820299 =State Loc 26 (MICHIGAN)
Carrier/Loc 0620200 =State Loc 27 (MINNESOTA)
Carrier/Loc 0730200 =State Loc 28 (MISSISSIPPI)
Carrier/Loc 0530202 =State Loc 29 (MISSOURI)
Carrier/Loc 0530201 =State Loc 29 (MISSOURI)
Carrier/Loc 0530299 =State Loc 29 (MISSOURI)
Carrier/Loc 0320201 =State Loc 30 (MONTANA)
Carrier/Loc 0540200 =State Loc 31 (NEBRASKA)
Carrier/Loc 0131200 =State Loc 32 (NEVADA)
Carrier/Loc 1431240 =State Loc 33 (NEW HAMPSHIRE)
Carrier/Loc 1240201 =State Loc 34 (NEW JERSEY)
Carrier/Loc 1240299 =State Loc 34 (NEW JERSEY)
Carrier/Loc 0421205 =State Loc 35 (NEW MEXICO)
Carrier/Loc 1320201 =State Loc 36 (NEW YORK)
Carrier/Loc 1320202 =State Loc 36 (NEW YORK)
Carrier/Loc 1320203 =State Loc 36 (NEW YORK)
Carrier/Loc 1329204 =State Loc 36 (NEW YORK)
Carrier/Loc 1328299 =State Loc 36 (NEW YORK)
Carrier/Loc 1150200 =State Loc 37 (NORTH CAROLINA)
Carrier/Loc 0330201 =State Loc 38 (NORTH DAKOTA)
Carrier/Loc 1520200 =State Loc 39 (OHIO)
Carrier/Loc 0431200 =State Loc 40 (OKLAHOMA)
Carrier/Loc 0230201 =State Loc 41 (OREGON)
Carrier/Loc 0230299 =State Loc 41 (OREGON)
Carrier/Loc 1250201 =State Loc 42 (PENNSYLVANIA)
Carrier/Loc 1250299 =State Loc 42 (PENNSYLVANIA)
Carrier/Loc 0920220 =State Loc 72 (PUERTO RICO)
Carrier/Loc 1441201 =State Loc 44 (RHODE ISLAND)
Carrier/Loc 1120201 =State Loc 45 (SOUTH CAROLINA)
Carrier/Loc 0340202 =State Loc 46 (SOUTH DAKOTA)
Carrier/Loc 1030235 =State Loc 47 (TENNESSEE)
Carrier/Loc 0441231 =State Loc 48 (TEXAS)
Carrier/Loc 0441220 =State Loc 48 (TEXAS)
Carrier/Loc 0441209 =State Loc 48 (TEXAS)
Carrier/Loc 0441211 =State Loc 48 (TEXAS)
Carrier/Loc 0441228 =State Loc 48 (TEXAS)

Carrier/Loc 0441215 =State Loc 48 (TEXAS)
Carrier/Loc 0441218 =State Loc 48 (TEXAS)
Carrier/Loc 0441299 =State Loc 48 (TEXAS)
Carrier/Loc 0350209 =State Loc 49 (UTAH)
Carrier/Loc 1451250 =State Loc 50 (VERMONT)
Carrier/Loc 0920250 =State Loc 78 (VIRGIN ISLANDS)
Carrier/Loc 1130200 =State Loc 51 (VIRGINIA)
Carrier/Loc 0240202 =State Loc 53 (WASHINGTON)
Carrier/Loc 0240299 =State Loc 53 (WASHINGTON)
Carrier/Loc 1140216 =State Loc 54 (WEST VIRGINIA)
Carrier/Loc 0630200 =State Loc 55 (WISCONSIN)
Carrier/Loc 0360221 =State Loc 56 (WYOMING)

50.5 - Jurisdiction of Laboratory Claims

(Rev. 3071, Issued: 09-19-14, Effective: 12-22-14, Implementation: 12-22-14)

Jurisdiction of payment requests for laboratory services furnished by an independent laboratory, except where indicated in §50.5.1 and §50.5.2, lies with the A/B MAC (B) serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides services to customers outside its A/B MAC (B)'s service area. The location where the independent laboratory performed the test determines the 50.appropriate billing jurisdiction. Therefore, even if the sample originates in a different jurisdiction from where the sample is being tested, the claim would still be filed in the jurisdiction where the test was performed.

Claims filing jurisdiction for the specimen collection fee and travel allowance is also determined by the location where the test was performed. When billed by an independent lab, the specimen collection fee and travel allowance must be billed in conjunction with a covered lab test. For more information about the specimen collection fee and travel allowance, see §60.1 and §60.2, respectively.

50.5.1 - Jurisdiction Of Referral Laboratory Services

(Rev. 85, 02-06-04)

Regardless of whether the laboratory that bills Medicare is the referring or reference laboratory, the laboratory that does the billing may bill only the A/B MAC (B) that services the jurisdiction in which the billing laboratory is physically located. The location of the draw station, when a separate draw station is employed, never determines claims filing jurisdiction.

50.5.2 - Examples of Reference Laboratory Jurisdiction Rules

(Rev. 85, 02-06-04)
B3-3102

EXAMPLE 1:

Scenario 1:

An independent laboratory located in Oregon performs laboratory services for physicians whose offices are located in several neighboring States. A physician from Nevada sends specimens to the Oregon laboratory.

Jurisdiction: The A/B MAC (B) in Oregon has jurisdiction.

EXAMPLE 2:

Scenario 2: American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

The Philadelphia laboratory receives a blood sample from a patient whose physician ordered a complete blood count, a basic metabolic panel and a B12 and folate. The Philadelphia laboratory performs the complete blood count, but the basic metabolic panel is performed at the Millville laboratory, while the B12 and folate is performed at the Boston Laboratory.

Jurisdiction: The Pennsylvania A/B MAC (B) may retain jurisdiction for processing the claim for all of the services. The A/B MAC (B) servicing Boston and/or Millville may have jurisdiction for processing their claims if those laboratories bill for the services they perform, but the Philadelphia laboratory is barred from billing for the services that Boston and Millville submit for payment.

EXAMPLE 3:

Scenario 3: Same relationships as in Example 2. American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

This time the Wilmington laboratory draws a blood specimen from a patient whose physician has ordered a blood culture. The Wilmington laboratory then sends the specimen to the Boston laboratory, which performs the required test.

Jurisdiction: The A/B MAC (B) processing claims for providers/suppliers located in Delaware may retain jurisdiction for processing the claim. If the laboratory in Boston chooses to bill for the service to the Massachusetts A/B MAC (B), then the Wilmington laboratory may not bill for the service.

60 - Specimen Collection Fee and Travel Allowance

(Rev. 1, 10-01-03)
B3-5114.1

60.1 - Specimen Collection Fee

(Rev. 1, 10-01-03)
B3-5114.1, A3-3628

In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish a nominal fee to cover the appropriate costs of collecting the sample on which a clinical laboratory test was performed and for which payment is made with respect to samples collected in the same encounter.

A specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

60.1.1 - Physician Specimen Drawing

(Rev. 1, 10-01-03)
HO-437, A3-3628, B3-5114.1

Medicare allows a specimen collection fee for physicians only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.

60.1.2 - Independent Laboratory Specimen Drawing

(Rev. 3071, Issued: 09-19-14, Effective: 12-22-14, Implementation: 12-22-14)

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another.

Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. Payment for the specimen collection fee is made based on the clinical laboratory fee schedule. The technician must personally draw the specimen, e.g., venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary. (See Chapters 7 and 15 of Pub. 100-02, the Medicare Benefit Policy Manual for a discussion of “homebound” and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

In addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing or EKG services prescribed by a physician should be appropriately annotated, e.g., "patient confined to home," "patient homebound," or "patient in nursing home, no qualified person on duty to draw specimen." A/B MACs (B) must assure the validity of the annotation through scientific claims samples as well as through regular bill review techniques. (This could be done by use of the information in A/B MAC (B) files, and where necessary, contact with the prescribing physician.)

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met.

The specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.

60.1.3 - Specimen Drawing for Dialysis Patients

(Rev. 3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite rate. With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. A specimen collection fee determined by CMS will be allowed only in the following circumstances:

- Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).

- Collecting a urine sample by catheterization.

Special rules apply when such services are furnished to dialysis patients. The specimen collection fee is not separately payable for patients dialyzed in the facility or for patients dialyzed at home under reimbursement Method I. A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements. Payment for specimen collection is included under the ESRD PPS, regardless of whether the laboratory test itself is included in the ESRD PPS or is separately billable with the AY modifier (see §40.6 of this chapter).

Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD composite rate may be paid separately.

60.1.4 - Coding Requirements for Specimen Collection

(Rev. 3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)

The following HCPCS codes and terminology must be used:

- 36415 - Collection of venous blood by venipuncture.
- G0471 - Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)
- P96l5 - Catheterization for collection of specimen(s).

The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS.

60.2 - Travel Allowance

(Rev. 4495, Issued:01-17-20, Effective:01-01-20, Implementation:02-18-20)

In addition to a specimen collection fee allowed under §60.1, Medicare, under Part B, covers a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under §1833(h)(3) of the Act and payment is made based on the clinical laboratory fee schedule. The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.

The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.

The travel allowance is not distributed by CMS. Instead, the carrier must calculate the travel allowance for each claim using the following rules for the particular Code. The following HCPCS codes are used for travel allowances:

Per Mile Travel Allowance (P9603)

- The minimum "per mile travel allowance" is $1.03. The per mile travel allowance is to be used in situations where the average trip to patients' homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip. - one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; prorated miles actually traveled (carrier allowance on per mile basis); or
- The per mile allowance was computed using the Federal mileage rate plus an additional 45 cents a mile to cover the technician's time and travel costs (57.5 cents plus 45 cents equals 1.025 cents and is rounded up to 1.03 cents per mile to reflect system capabilities). Contractors have the option of establishing a higher

per mile rate in excess of the minimum ($1.03 a mile in CY 2020) if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the clinical lab fee schedule as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

Example 1: In CY 2020, a laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location, and back to the lab to draw a single Medicare patient's blood. The total reimbursement would be $61.80 (60 miles x $1.03 a mile), plus the specimen collection fee.

Example 2: In CY 2020, a laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, and then travels an additional 10 miles to a non-Medicare patient's home and then travels 30 miles to return to the lab. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled or $41.20 (40 x $1.03), plus the specimen collection fee.

Flat Rate (P9604)

The CMS will pay a minimum of $10.30 (based on CY 2020) one way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. The flat rate travel fee is to be pro-rated for more than one blood drawn at the same address, and for stops at the homes of Medicare and non-Medicare patients. The laboratory does the pro-ration when the claim is submitted based on the number of patients seen on that trip. The specimen collection fee will be paid for each patient encounter.

This rate is based on an assumption that a trip is an average of 15 minutes and up to 10 miles one way. It uses the Federal mileage rate and a laboratory technician's time of $17.66 an hour, including overhead. Contractors have the option of establishing a flat rate in excess of the minimum of $10.00, if local conditions warrant it. The minimum national flat rate will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as necessitated by adjustments in the Federal travel allowance and salaries.

The claimant identifies round trip travel by use of the LR modifier

Example 3: A laboratory technician travels from the laboratory to a single Medicare patient's home and returns to the laboratory without making any other stops. The flat rate would be calculated as follows: 2 x $10.30 for a total trip reimbursement of $20.60, plus the specimen collection fee.

Example 4: A laboratory technician travels from the laboratory to the homes of five patients to draw blood, four of the patients are Medicare patients and one is not. An additional flat rate would be charged to cover the 5 stops and the return trip to the lab (6 x $10.30 = $61.80). Each of the claims submitted would be for $12.36 ($61.80/5 = $12.36). Since one of the patients is non-Medicare, four claims would be submitted for $12.36 each, plus the specimen collection fee for each.

Example 5: A laboratory technician travels from a laboratory to a nursing home and draws blood from 5 patients and returns to the laboratory. Four of the patients are on Medicare and one is not. The $10.30 flat rate is multiplied by two to cover the return trip to the laboratory (2 x $10.30 = $20.60) and then divided by five (1/5 of $20.60 = $4.12). Since one of the patients is non-Medicare, four claims would be submitted for $4.12 each, plus the specimen collection fee.

If a carrier determines that it results in equitable payment, the carrier may extend the former payment allowances for additional travel (such as to a distant rural nursing home) to all circumstances where travel is required. This might be appropriate, for example, if the carrier's former payment allowance was on a per mile basis. Otherwise, it should establish an appropriate allowance and inform the suppliers in its service area. If a carrier decides to establish a new allowance, one method is to consider developing a travel allowance consisting of:

- The current Federal mileage allowance for operating personal automobiles, plus a personnel allowance per mile to cover personnel costs based upon an estimate of average hourly wages and average driving speed.

Carriers must prorate travel allowance amounts claimed by suppliers by the number of patients (including Medicare and non-Medicare patients) from whom specimens were drawn on a given trip.

The carrier may determine that payment in addition to the routine travel allowance determined under this section is appropriate if:

- The patient from whom the specimen must be collected is in a nursing home or is homebound; and

- The clinical laboratory tests are needed on an emergency basis outside the general business hours of the laboratory making the collection.

- Subsequent updated travel allowance amounts will be issued by CMS via Recurring Update Notification (RUN) on an annual basis.

70 - Clinical Laboratory Improvement Amendments (CLIA) Requirements

(Rev. 1, 10-01-03)
A3-3628.2, RHC-640, ESRD 322, HO-306, HHA-465, SNF 541, HO-437.2, PM B-97-3

70.1 - Background

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

The Clinical Laboratory Improvements Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (PHSA) to extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that examine human specimens to provide information to assess, diagnose, prevent, or treat any disease or impairment. The purpose of the CLIA program is to assure that laboratories testing specimens in interstate commerce consistently provide accurate procedures and services. As a result of CLIA, any laboratory soliciting or accepting specimens in interstate commerce for laboratory testing is required to hold a valid license or letter of exemption from licensure issued by the Secretary of HHS. The term “interstate commerce” means trade, traffic, commerce, transportation, or communication between any state, possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

The CLIA mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs. CLIA also lists requirements for laboratories performing only certain tests to be eligible for a certificate of waiver or a certificate for Physician Performed Microscopy Procedures (PPMP). Since 1992, A/B MACs (B) have been instructed to deny clinical laboratory services billed by independent laboratories which did not meet the CLIA requirements. POLs were excluded from the 1992 instruction but included in 1997.

The CLIA number must be included on each claim billed on the ASC X12 837 professional format or Form CMS-1500 claim for laboratory services by any laboratory performing tests covered by CLIA. See §70.2 and 70.10 for more information.

70.2 - Billing

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

See §70.10 for instructions for reporting the CLIA number.

70.3 - Verifying CLIA Certification

(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

CWF edits A/B MAC (B) claims to ascertain that the laboratory identified by the CLIA number is certified to perform the test. (CWF uses data supplied from the certification process.) See Chapter 27 for related specifications.

Providers that bill A/B MACs (A) are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that these providers have procedures in place to insure that laboratory services are provided by CLIA approved laboratories.

Refer to the Medicare State Operations Manual for information about CLIA license or the CLIA licensure exemptions.

70.4 - CLIA Numbers

(Rev. 1, 10-01-03)
A3-3628.2.D

The structure of the CLIA number follows:

Positions 1 and 2 contain the State code (based on the laboratory's physical location at time of registration);

Position 3 contains the letter "D"; and

Positions 4-10 contain the unique CLIA system assigned number that identifies the laboratory. (No other laboratory in the country has this number.)

Initially, providers are issued a CLIA number when they apply to the CLIA program.

Independent dialysis facilities must obtain a CLIA certificate in order to perform clotting time tests.

70.5 - CLIA Categories and Subcategories

(Rev. 1, 10-01-03)

A laboratory may be licensed or exempted from licensure in several major categories of procedures. These major categories are:

Category Number	Category/Subcategory Name
010	Histocompatibility
100	Microbiology
110	Bacteriology

Category Number	Category/Subcategory Name
115	Mycobacteriology
120	Mycology
130	Parasitology
140	Virology
150	Other Microbiology
200	Diagnostic Immunology
210	Syphilis Serology
220	General Immunology
300	Chemistry
310	Routine
320	Urinalysis
330	Endocrinology
340	Toxicology
350	Other
400	Hematology
500	Immuno-hematology
510	ABO Group and RH Type
520	Antibody Detection (Transfusion)
530	Antibody Detection (Non Transfusion)
540	Antibody Identification
550	Compatability Testing
560	Other
600	Pathology
610	Histopathology

Category Number	Category/Subcategory Name
620	Oral Pathology
630	Cytology
800	Radioassay
900	Clinical Cytogenics

For a list of specific HCPCS codes see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

70.6 - Certificate for Provider-Performed Microscopy Procedures

(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

Effective January 19, 1993, a laboratory that holds a certificate for provider-performed microscopy procedures may perform only those tests specified as provider-performed microscopy procedures and waived tests, as described below, and no others.

HCPCS Code	Test
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous
81015	Urinalysis; microscopic only
81000	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)
81020	Urinalysis; two or three glass test

89055	Fecal leukocyte examination
89190	Nasal smears for eosinophils
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner

70.7 - Deleted - Held for Expansion
(Rev. 1, 10-01-03)

70.8 - Certificate of Waiver
(Rev. 1652, Issued: 12-19-08, Effective: 01-01-09, Implementation: 01-05-09)

Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.

The Food and Drug Administration approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the A/B MACs (A) and (B) on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

For a list of specific HCPCS codes subject to CLIA see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/SubjecttoCLIA.pdf

70.9 - HCPCS Subject To and Excluded From CLIA Edits
(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

At this time, all claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the HCPCS codes that are considered a laboratory test under CLIA change each year. The CMS identifies the new HCPCS (non-waived, non-provider-performed procedure) codes, including any modifiers that are subject to CLIA edits by providing an updated listing of these tests to the A/B MACs (A) and (B) on an annual basis via a Recurring Update Notification. A facility that submits a claim for any test mentioned in the HCPCS codes that are subject to CLIA edits list must have either a valid, current CLIA certificate of registration (certificate type 9), a CLIA certificate of compliance (certificate type 1), or a CLIA certificate of accreditation (certificate type 3).

For a list of the specific HCPCS codes subject to CLIA edits refer to the following Internet site: http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf

In addition, the CMS identifies the new HCPCS codes in the 80000 series that are excluded from CLIA edits by providing an updated listing of these tests to the A/B MACs (A) and (B) on an annual basis via a Recurring Update Notification. No CLIA

certificate is required for a claim submitted for any test mentioned in the HCPCS codes in the 80000 series that are excluded from CLIA edits list.

For a list of the specific HCPCS codes in the 80000 series that are excluded from CLIA edits refer to the following Internet site:
http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf

70.10 - CLIA Number Submitted on Claims from Independent Labs

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Effective with services provided October 1, 1997, any independent laboratory performing tests covered by CLIA must submit the CLIA number on the claim as provided below. The CLIA number is reported in:

- ASC X12 837 professional claim format REF segment as REF02, with qualifier of “X4” in REF01, or
- Field 23 of the paper CMS-1500.

The CLIA number is not required on the ASC X12 institutional claim data set or its related paper Form CMS-1450.

See Chapter 26 for detailed format instructions for the paper claim CMS-1500.

Laboratory claims submitted without the required CLIA number are returned as unprocessable. If the CLIA number is submitted on the claim, but is inconsistent with the CLIA format, the A/B MAC (B) returns the claim as unprocessable. If more than one CLIA number is submitted on the claim, except when a reference laboratory is on the same claim, the A/B MAC (B) returns the claim as unprocessable.

If the tests on one claim have been performed in more than one Physician Office Laboratory (POL) by the same physician, the appropriate CLIA number should be associated with the test that was performed in each laboratory. In such a case, the physician must submit a separate claim for each location (CLIA number) where a test was performed.

70.10.1 - Physician Notification of Denials

(Rev. 3510, Issued: 04-29-16, Effective: 10-01-16, Implementation; 10-03-16)

If there is no CLIA number on the claim, the contractor shall use the following remittance advice message and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two

Group Code: CO or PR
CARC: 16
RARC: MA120
MSN: N/A

70.11 - Reasons for Denial - Physician Office Laboratories Out-of-Compliance

(Rev. 3510, Issued: 04-29-16, Effective: 10-01-16, Implementation; 10-03-16)

The contractor shall use the following remittance advice message and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: B7
RARC: N/A
MSN: 14.1

80 - Issues Related to Specific Tests

(Rev. 1, 10-01-03)

80.1 - Screening Services

(Rev. 1, 10-01-03)

See chapter 18 for payment, edit and MSN requirements for the following screening services.

- Screening Pap Smear and Pelvic Examination
- Screening Prostate Tests
- Colorectal Cancer Screening

80.2 - Anatomic Pathology Services

(Rev. 1, 10-01-03)
A3-3628.1, SNF 541.1, HO-437.1, RHC-437, CIM 50.20.1, PM AB-98-7, AB-98-22, B-98-16, A-98-6, R103.CIM, A3-4603.1

Clinical laboratory tests include some services described as anatomic pathology services in CPT (i.e., certain cervical, vaginal, or peripheral blood smears). The CPT code 85060 is used only when a physician interprets an abnormal peripheral blood smear for a hospital inpatient or a hospital outpatient, and the hospital is responsible for the technical component. When an independent laboratory bills a physician interpretation of an abnormal peripheral blood smear, the service is considered a complete or global service, and is not billed under the CPT code 85060. A physician interpretation of an abnormal peripheral blood smear performed by an independent laboratory is considered a routine part of the ordered hematology service (i.e., those tests that include a different white blood count).

The HCPCS code 88150 (cervical or vaginal smears) included both screening and interpretation in CPT 1986 terminology while the CPT 1987 terminology includes only screening. A new code, 88151, was added for those smears that require physician interpretation. Code 88151 is treated and priced in the same manner as code 88150 was previously treated and priced. Code 88151 with a “-26” modifier is paid when a

physician performs an interpretation of an abnormal smear for a hospital inpatient or outpatient, and the hospital is responsible for the technical component. The "-26" modifier for code 88150 is no longer recognized. Code 88151(26) is priced as code 88150(26) would have been priced if the coding terminology had not been revised. Independent laboratories bill under code 88150 for normal smears and under code 88151 for abnormal smears. However, the fee schedule amount is equivalent.

80.2.1 - Technical Component (TC) of Physician Pathology Services to Hospital Patients

(Rev. 2714, Issued: 05-24-13, Effective: 07-01-12 Implementation: 06-25, 13)

Section 542 of the Benefits Improvement and Protection Act of 2000 (BIPA) provides that the A/B MAC(B) can continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. This provision applies to TC services furnished during the 2-year period beginning on January 1, 2001. Administrative extensions of this provision, and new provisions established under Section 732 of the Medicare Modernization Act (MMA); Section 104 of the Tax Relief and Health Care Act (TRHCA) of 2006; Section 104 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA); Section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA); Section 3104 of the Patient Protection and Affordable Care Act (PPACA); Section 105 of the Medicare & Medicaid Extenders Act of 2010 (MMEA); and Section 3006 of the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA) allow the A/B MAC (B) to continue to pay for this service through June 30, 2012.

For this provision, covered hospital means a hospital that had an arrangement with an independent laboratory or other entity that was in effect as of July 22, 1999, under which the laboratory or other entity furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients and submitted claims for payment for the TC to an A/B MAC (B). The TC could have been submitted separately or combined with the professional component and reported as a combined service.

The term "fee-for-service Medicare beneficiary" means an individual who:

1. Is entitled to benefits under Part A or enrolled under Part B of title XVIII or both;

and

2. Is not enrolled in any of the following:

    a. A Medicare + Choice plan under Part C of such title;

    b. A plan offered by an eligible organization under §1876 of the Act;

    c. A program of all-inclusive care for the elderly under §1894 of the Act; or

    d. A social health maintenance organization demonstration project established under §4108(b) of the Omnibus Budget Reconciliation Act of 1987.

The following examples illustrate the application of the statutory provision to arrangements between hospitals and independent laboratories and/or other entities.

In implementing BIPA §542; MMA §732; TRHCA §104; MMSEA §104; MIPPA §136; and PPACA § 3104; MMEA § 105; and MCTRJCA § 3006, the A/B MAC (B) should consider as independent laboratories any entity that it has previously recognized and paid as an independent laboratory as of July 22, 1999.

An independent laboratory that has acquired another independent laboratory that had an arrangement on July 22, 1999, with a covered hospital, can bill the TC of physician pathology services for that hospital's inpatients and outpatients under the physician fee schedule through June 30, 2012.

EXAMPLE 1:

Prior to July 22, 1999, independent laboratory A had an arrangement with a hospital in which this laboratory billed the A/B MAC (B) for the TC of physician pathology services. In July 2000, independent laboratory B acquires independent laboratory A. Independent laboratory B bills the A/B MAC (B) for the TC of physician pathology services for this hospital's patients in 2001 and forward.

If a hospital is a covered hospital, any independent laboratory that furnishes the TC of physician pathology services to that hospital's inpatients or outpatients can bill the A/B MAC (B) for these services furnished in 2001 and forward up to June 30, 2012 (see note below on last paragraph).

EXAMPLE 2:

As of July 22, 1999, the hospital had an arrangement with an independent laboratory, laboratory A, under which that laboratory billed the A/B MAC (B) for the TC of physician pathology service to hospital inpatients or outpatients. In 2001, the hospital enters into an arrangement with a different independent laboratory, laboratory B, under which laboratory B wishes to bill its A/B MAC (B) for the TC of physician pathology services to hospital inpatients or outpatients. Because the hospital is a "covered hospital," independent laboratory B can bill its A/B MAC (B) for the TC of physician pathology services to hospital inpatients or outpatients.

If the arrangement between the independent laboratory and the covered hospital limited the provision of TC physician pathology services to certain situations or at particular times, then the independent laboratory can bill the A/B MAC (B) only for these limited services.

An independent laboratory that furnishes the TC of physician pathology services to inpatients or outpatients of a hospital that is not a covered hospital may not bill the A/B MAC (B) for TC of physician pathology services furnished to patients of that hospital.

An independent laboratory or other entity that has an arrangement with a covered hospital should forward a copy of this agreement or other documentation to its A/B MAC (B) to

confirm that an arrangement was in effect between the hospital and the independent laboratory as of July 22, 1999. This documentation should be furnished for each covered hospital the independent laboratory or other entity services. If the laboratory or other entity did not have an arrangement with the covered hospital as of July 22, 1999, but has subsequently entered into an arrangement, then it should obtain a copy of the arrangement between the predecessor laboratory or other entity and the covered hospital and furnish this to the A/B MAC (B). The A/B MAC (B) maintains a hard copy of this documentation for postpayment reviews.

Please Note: Effective on or after July 1, 2012, only the hospital may bill for the TC of a physician pathology service provided to an inpatient or outpatient. Neither example 1 nor example 2 above will apply for claims with dates of service on or after July 1, 2012.

80.3 - National Minimum Payment Amounts for Cervical or Vaginal Smear Clinical Laboratory Tests

(Rev. 1, 10-01-03)
PM AB-99-84, AB-99-99

For cervical or vaginal smear clinical laboratory tests, payment is the lesser of the local fee or the national limitation amount, but not less than the national minimum payment amount (NMPA). However, in no case may payment for these tests exceed actual charges. The Part B deductible and coinsurance do not apply.

For tests performed on or after January 1, 2000, a NMPA of $14.60 is established and applies for cervical or vaginal smear clinical laboratory tests in accordance with §224 of the Balanced Budget Refinement Act (Public Law 106-113). The affected CPT laboratory test codes for the NMPA are 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, G0123, G0143, G 0144, G0145, G0147, G0148, and P3000.

The NMPA will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as required. Instructions for such updates will be sent to A/B MACs (A) and (B) through periodic temporary instructions.

80.4 - Oximetry

(Rev. 1, 10-01-03)
B3-5114.1

Certain blood gas levels are determined either by invasive means through use of a blood specimen for a clinical laboratory test or by noninvasive means through ear or pulse oximetry, which is not considered a clinical laboratory test. CPT code 82792 is used for invasive oximetry. HCPCS code M0592 is used for ear and pulse oximetry. Code M0592 is not subject to fee schedules.

90 - Automated Profile Tests and Organ/Disease Oriented Panels

(Rev. 1, 10-01-03)

The term “profile” or “panel” means a grouping of laboratory tests, which is usually performed automatically on a single piece of testing equipment.

90.1 - Laboratory Tests Utilizing Automated Equipment

(Rev. 4299; Issued: 05-03-19; Effective: 01-01-19; Implementation: 10-07-19)
B3-5114, HO-437, A3-3628

Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. Because of the numerous technological advances and innovations in the clinical laboratory field and the increased availability of automated testing equipment, no distinction is generally made in determining payment for individual tests because of either (1) the sites where the service is performed, or (2) the method of the testing process used, whether manual or automated. Whether the test is actually performed manually or with automated equipment, the services are considered similar and the payment is the same.

90.1.1 - Automated Test Listing

(Rev. 4299, Issued: 05-03-19, Effective: 01-01-19, Implementation: 10-07-19)
B3-5114, HO-437, A3-3628, PMs AB-97-5, AB-97-7, AB-97-17

Profiles are specific groupings of blood chemistries that enable physicians to more accurately diagnose their patients’ medical problems. While the component tests in automated profiles may vary somewhat from one laboratory to another, or from one physician’s office or clinic to another, in order to develop appropriate payment amounts, A/B MACs (A) and (B) group together those profile tests that can be performed at the same time on the same equipment. The A/B MAC (A) or (B) must group together the individual tests in the profile when billed separately and consider the price of the related automated profile test. Payment cannot exceed the lower of the profile price or the totals of the prices of all the individual tests. (This rule is applicable also if the tests are done manually.) The profile HCPCS code and each individual test is priced at the lower of the billed charge or the fee amount; and payment is made at the lower of the profile/panel price or the total of the prices for all covered components.

Payment is made only for those tests in an automated profile that meet Medicare coverage rules. Where only some of the tests in a profile of tests are covered, payment cannot exceed the amount that would have been paid if only the covered tests had been ordered. For example, the use of the 12-channel serum chemistry test to determine the blood sugar level in a proven case of diabetes is unreasonable because the results of a blood sugar test performed separately provide the essential information. Normally, the payment allowance for a blood sugar test is lower than the payment allowance for the automated profile of tests. In no event, however, may payment for the covered tests exceed the payment allowance for the profile.

However, the A/B MAC (B) prices and pays the 1-22 automated multi-channel chemistry tests tested in §90.2 at the lowest possible amount in accordance with §90.3.

As of January 1, 2018, the profiles referenced in the above section are no longer recognized by Medicare. The Protecting Access to Medicare Act of 2014 requires Medicare to pay a weighted median collected from private payor rates for each

HCPCS code on the CLFS. Therefore the automated profiles described above are no longer used to pay for the automated profiles of tests.

90.2 - Organ or Disease Oriented Panels

(Rev. 4299, Issued: 05-03-19, Effective: 01-01-19, Implementation: 10-07-19)

Prior to January 1, 2018, organ or disease panels must be paid at the lower of the billed charge, the fee amount for the panel, or the sum of the fee amounts for all components. Payment for the total panel may not exceed the sum total of the fee amounts for individual covered tests. All Medicare coverage rules apply.

The Medicare shared systems must calculate the correct payment amount. The CMS furnishes fee prices for each code but the A/B MAC (A) or (B) system must compare individual codes billed with codes and prices for related individual tests. (With each HCPCS update, HCPCS codes are reviewed and the system is updated). Once the codes are identified, A/B MACs (A) and (B) publish panel codes to providers.

The only acceptable Medicare definition for the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association (AMA) definition of component tests. The CMS will not pay for the panel code unless all of the tests in the definition are performed. If the laboratory has a custom panel that includes other tests, in addition to those in the defined CPT or HCPCS panels, the additional tests, are billed separately in addition to the CPT or HCPCS panel code.

NOTE: If a laboratory chooses, it can bill each of the component tests of these panels individually, but payment will be based upon the above rules.

Effective for claims with dates of service on or after January 1, 2019, laboratories shall bill the HCPCS panel test code and not unbundle the individual components if all components of the HCPCS panel are performed. Claims will be returned as unprocessable/rejected if the HCPCS panel test code is not billed. Providers and suppliers are required to submit all AMCC laboratory test HCPCS for the same beneficiary, performed on the same date of service on the same claim. This billing policy applies when:

a). Submitting a complete organ disease panel; or

b). Submitting individual component tests of an organ disease panel when all components of the panel were not performed.

TABLE OF CHEMISTRY PANELS

		Hepatic Function Panel 80076	**Basic Metabolic Panel** (Calcium, ionized) **80047**	**Basic Metabolic Panel** (Calcium, total) **80048**	**Comprehensive Metabolic Panel 80053**	**Renal Function Panel 80069**	**Lipid[1] Panel 80061**	**Electrolyte Panel 80051**
Chemistry	**CPT**							
Albumin	82040	X			X	X		
Alkaline phosphatase	84075	X			**X**			
ALT (SGPT)	84460	X			X			
AST (SGOT)	84450	X			X			
Bilirubin, total	82247	X			X			
Bilirubin, direct	82248	X						
Calcium	82310			X	X	X		
Calcium ionized	82330		X					
Chloride	82435		X	X	X	X		X
Cholesterol	82465						X	
CK, CPK	82550							
CO2 (bicarbonate)	82374		X	X	X	X		X
Creatinine	82565		X	X	X	X		
GGT	82977							
Glucose	82947		X	X	X	X		
LDH	83615							
Phosphorus	84100					X		
Potassium	84132		X	X	X	X		X
Protein	84155	X			X			
Sodium	84295		X	X	X	X		X
Triglycerides	84478						X	
Urea nitrogen (BUN)	84520		X	X	X	X		
Uric Acid	84550							

90.3 - Claims Processing Requirements for Panel and Profile Tests
(Rev. 4299, Issued: 05-03-19, Effective: 01-01-19, Implementation: 10-07-19)

All test codes should be processed and stored in history as they are submitted. That is, if tests are submitted as individual CPT codes together and paid as a panel (see §90), the claim history data will reflect the individual codes and the panel used in pricing. All tests must maintain their identity as billed.

Prior to January 1, 1998, automated panel codes were adjudicated only on a line-by-line basis with application of the correct coding initiative (CCI) edits for duplicate detection.

As of January 1, 1998, when individual automated test codes are received, A/B MACs (A) and (B) did not combine them into panels for processing. The only instance in which they should be panel codes is when they were coded as such on the claim.

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[1] CPT code 83718 is billed with Organ/Disease Panel 80061 but is not included in the AMCC bundling.

Beginning January 1, 2018, Medicare does not recognize automated test panels, unless a panel has its own CPT code, as described in section 90.2.

A/B MACs (A) and (B)

1. Deny Duplicates. Deny duplicate services detected within the same processing cycle or stored in an automated history file. Consider claims that match on the following items as duplicates

a. The service was performed by the same provider,
b. For the same beneficiary, and
c. For the same date of service.

2. Medical Necessity. Determine medical necessity. This process permits the identification of CPT codes subject to local medical review policies.

3. Process Claims. For claims with dates of service prior to January 1, 2019, the processes shown below **(A-K)** should be followed to price and pay claims for automated panels (as defined in HCPCS) and individual tests. This does not replace or abridge any current procedures in place concerning the adjudication of claim. This is a general procedure for combining these services to attain the lowest pricing outcome. This display is an example only. System maintainers have the flexibility to vary these procedures as long as they attain the same result.

A. Unbundle all panels to single lines representing individual automated multi-channel chemistry (AMCC) tests, and identify duplicate tests within the claim. On concurrently processed claims, determine the total amount payable based on the combination of all AMCC tests billed by the same laboratory, for the same beneficiary, and for the same date of service.

B. Check history for laboratory AMCC services provided by the same provider, to the same beneficiary, on the same day. Unbundle any panels. Identify duplicate services. Aggregate all nonduplicate services for pricing (include the submitted charge and paid amounts for both individually or paneled billed claims). If a single organ disease panel or a single chemistry panel contains the only AMCC test claims for that date of service, adjudicate as billed.

C. Compare each line's submitted charge to the fee schedule for that code (including automated tests retrieved from history).

D. Sum the comparisons of the line by line.

E. Obtain the fee for all AMCC tests as a panel including all services in history. If organ disease (OD) panels are involved, this amount will include fees for nonautomated tests included in the OD panel.

F. Carry forward the lesser of items D or E.

G. For steps A-C above, include the following calculations to price the claim by locality, using the fee schedule amount for each locality, when one or more test has been referred to another laboratory for processing:

Use the **total number of allowable AMCC tests** (both referred and nonreferred) to calculate the amount payable for each test. For example, if three tests are performed within the A/B MAC (A)'s or (B)'s jurisdiction, and two are referred to another laboratory for processing, first determine the amount payable for the five tests in each payment jurisdiction. Divide the total fee schedule amount for all tests being priced by the total number of allowable AMCC tests (in this example, five tests). The result is the unit price for each test. Multiply this result by the total number of AMCC tests performed within each pricing jurisdiction. (In this example, three tests were performed in jurisdiction 1 and two tests were performed in jurisdiction 2). Repeat this process for each pricing jurisdiction. In this example, there are two pricing jurisdictions. In jurisdiction 1, the amount payable is calculated by dividing the total fee schedule amount for jurisdiction 1 by five, and multiplying the result by three. Similarly, the amount payable for jurisdiction 2 is calculated by dividing the total fee schedule amount for jurisdiction 2 by five, and multiplying the result by two. Sum the two results (i.e., jurisdiction 1 amount + jurisdiction 2 amount). Compare this calculated amount to the submitted charges for the AMCC tests to determine the amount payable. (The amount payable is the lower of the fee schedule amount versus the submitted charges.)

H. Carry forward the lesser of the fee schedule amount versus the submitted charges, as determined in item G.

I. Subtract from item H any previous laboratory AMCC test (individual or paneled) or organ disease panel containing automated test payments. If nothing is payable on the claim, allow it with no payment.

J. The amount payable is the total payable based on the combination of current and previously processed claims, less the total amount paid on the previous claim(s).

K. If a claim is a CLIA reject from the CWF, recycle that claim through the payment process to recalculate payment.

(**NOTE:** These calculations are provided as an example only. A/B MACs (A) and (B) and shared system maintainers have the flexibility to vary these procedures as long as they attain the same result.)

If none of the AMCC tests have been referred to another laboratory for processing, A/B MACs (A) and (B) should exclude item G in calculating the amounts payable for individual AMCC tests and AMCC panels.

90.3.1 - History Display

(Rev. 4299, Issued: 05-03-19, Effective: 01-01-19, Implementation: 10-07-19)

Prior to January 1, 2018, when displaying claims payment for each CPT code in history, A/B MACs (A) and (B) apply the following rules:

1. If all component tests of any panel are allowed because the individual line item comparison is less than the fee (as determined in item C above), record the panel codes as determined on the line-by-line comparison.

2. If all component tests are paid based on the panel price, allocate the current payment proportionate to the amount submitted for each CPT code.

3. If any panel tests will be denied or there are previously paid automated laboratory tests (as indicated by a check of beneficiary history), allocate the current payment amount by allowed line proportionate to what was submitted for the current claim being processed.

For administration of pricing requirements and/or invalid coding policies, A/B MACs (A) and (B) must establish a processing sequence for concurrently processed claims based on ascending order of internal control number (ICN). In the case of pricing, they must process the "first claim" (i.e., lower CN) based solely on the billed codes on that claim, process the "second" claim based on a combination of the billed codes on both claims and pay the balance due after subtracting the amount paid on the "first" claim. In the case of unacceptable code combinations, A/B MACs (A) and (B) must deny the "second" claim.

90.3.2 - Medicare Secondary Payer
(Rev. 1, 10-01-03)

When processing claims involving Medicare secondary payer (MSP), A/B MACs (B) should use the MSP payment formula as follows:

When Medicare is secondary, Medicare pays the lowest of:

- The actual charge less the primary payment;
- The amount Medicare would pay if primary; or
- The higher of the Medicare or primary allowable less the primary payment.

The two-step pricing comparison described above is required for calculating MSP amounts.

90.4 - Evaluating the Medical Necessity for Laboratory Panel CPT Codes
(Rev. 1, 10-01-03)
PM-B-98-1

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) establishes three new and one revised Organ or Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multi-channel tests there is a general presumption of medical necessity. If A/B MACs (B) suspect abuse of the new panel codes, they should review such claims. Should an A/B MAC (B) determine the need to develop a LMRP for laboratory panel codes, the A/B MAC (B) should develop such a policy at the panel code level. As

appropriate, an A/B MAC (B) may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

90.5 - Special Processing Considerations

(Rev. 4299, Issued: 05-03-19, Effective: 01-01-19, Implementation: 10-07-19)
PM AB-97-17

To order any of the 23 automated tests, a physician may select individual tests or the panel. A physician may order a mix of panels and individual tests. The physician should review what tests are in each panel and not order individual tests that might duplicate tests in the panel. Medicare denies duplicate tests.

Specialists are not, based on their specialty, restricted to ordering certain panels or individual tests. The physician (general practitioner or specialist) should identify which tests he/she requires; and, if the tests match a grouping, order the appropriate panel.

Claimants should use the QP modifier with the single ordering of tests or when a single code is available for groupings of tests. This modifier indicates that the claimant has documentation on file showing that the laboratory test(s) was ordered individually or ordered as a CPT-recognized panel

100 - CPT Codes Subject to and Not Subject to the Clinical Laboratory Fee Schedule

(Rev. 1, 10-01-03)
HO-437, A3-3628, B3-5114.1

For fee schedule purposes, clinical laboratory services include most laboratory tests listed in codes 80048-89399 of CPT-1996. The CMS issues an update to the laboratory fee schedule each year, with information about whether prices have been determined by CMS or whether the individual A/B MAC (B) must determine the allowable charge.

Codes not included are not paid under the laboratory fee schedule but may be paid under the MPFS if covered for Medicare.

100.1 - Deleted - Held for Expansion

(Rev. 1, 10-01-03)

100.2 - Laboratory Tests Never Subject to the Fee Schedule

(Rev. 1, 10-01-03)

Some CPT codes in the 80000 series are not clinical laboratory tests and are therefore never subject to fee schedule limitations. Some of these codes are exempted because they are not clinical laboratory services. They include codes for procedures, services, blood products and auto-transfusions. They include codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate. Other codes for tests primarily associated with the provision of blood products are also not considered to be clinical tests. Such tests identify various characteristics of blood products, but are not diagnostic in nature. These include various blood cross matching techniques. If they are

covered, Medicare pays exclusion codes under the MPFS, reasonable charges, reasonable costs, or OPPS as applicable.

100.3 - Procedures Not Subject to Fee Schedule When Billed With Blood Products

(Rev. 1, 10-01-03)

The following codes are not subject to fee schedule limitations when submitted for payment on the same bill with charges for blood products. Rather, assume they are to be used for blood matching and not for diagnostic purposes.

Codes: 86901, 86905, 86930-86932, 86920-86922, 86890, 86870, 86891, 86880-86886, 86971, and 86930.

If no blood product is provided and billed for on the same claim, assume the codes are diagnostic and subject to the clinical laboratory fee schedule.

The shared system provides for this processing.

100.4 - Not Otherwise Classified Clinical Laboratory Tests

(Rev. 1, 10-01-03)

The following codes for unlisted or not otherwise classified (NOC) clinical laboratory tests are not subject to the NLA:

81099 87999
84999 88299
85999 89399
86999

The NOC codes shall suspend for review and the A/B MAC (B) shall determine a price for them.

100.5 - Other Coding Issues

(Rev. 1, 10-01-03)

100.5.1 - Tests Performed More Than Once on the Same Day

(Rev. 1, 10-01-03)
PM AB-98-7

When it is necessary to obtain multiple results in the course of treatment, the modifiers 59 or 91 are used to indicate that a test was performed more than once on the same day for the same patient. The 91 modifier is used for laboratory tests paid under the clinical laboratory fee schedule.

These modifiers may be used to indicate that a test was performed more than once on the same day for the same patient, only when it is necessary to obtain multiple results in the course of treatment. These modifiers may not be used when tests are rerun to confirm

initial results; due to testing problems with specimens and equipment; or for any other reason when a normal, one-time, reportable result is all that is required. These modifiers may not be used when there are standard HCPCS codes available that describe the series of results (e.g., glucose tolerance tests, evocative/suppression testing, etc.). These modifiers may be used only for laboratory tests paid under the clinical laboratory fee schedule.

Improper use of modifiers is likely to indicate a fraudulent or abusive circumstance. When informing laboratories of the availability of modifiers, A/B MACs (B) are to emphasize that these modifiers have very narrow application and that any evidence of excessive use will be referred to A/B MAC (A) or (B) Program Integrity Unit for further review.

100.6 - Pricing Modifiers

(Rev. 2487, Issued: 06-08-12, Effective: 01-01-11, Implementation: 06-19-12)

PM A-03-033

Prior to January 1, 2011

Three pricing modifiers discretely identify the different payment situations for ESRD Automated Multi-Channel Chemistry (AMCC) tests. The physician that orders the tests is responsible for identifying the appropriate modifier when ordering the tests. The modifiers are in the following listing:

- CD - AMCC test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable

- CE - AMCC test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity

- CF - AMCC test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable

The ESRD clinical laboratory tests identified with modifiers “CD,” “CE,” or “CF” may not be billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical laboratory tests must be billed individually.

Effective January 1, 2011

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate. If the ESRD facility needs to report a lab service that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD. Modifiers CD, CE, and CF (also known as the 50/50 rule modifiers) are no longer valid for use on independent laboratory claims.

Effective January 1, 2012, A/B MACs (B) shall allow organ disease panel codes (i.e., HCPCS codes 80047, 80048, 80051, 80053, 80061, 80069, and 80076) to be billed by independent laboratories for AMCC panel tests furnished to ESRD eligible beneficiaries.

For more information regarding billing of AMCC tests for ESRD beneficiaries, see Section 40.6.1 of this manual.

110 - Coordination Between A/B MACs (B) and Other Entities
(Rev. 1, 10-01-03)
B3-5114.1

110.1 - Coordination Between A/B MACs (B) and A/B MACs (A)/RRB
(Rev. 1, 10-01-03)

The A/B MAC (B) furnishes copies of fees that are locally established under the fee schedules (price code = 22) to A/B MACs (A) and to the RRB Specialty MAC (S MAC). The A/B MAC (B) must provide updates at least 30 days prior to the A/B MAC (B)'s scheduled implementation of the update. The A/B MACs (A) add these fees to system fee schedule tables to use in paying for hospital laboratory tests performed for both outpatients of the hospital and persons who are not patients of the hospital. The RRB S MAC uses the fee schedules in paying for outpatient clinical laboratory tests.

A/B MACs (A) and the RRB may consult with A/B MACs (B) on filling gaps in fee schedules for tests where the A/B MAC (B) may not have established an amount. If an A/B MAC (A) or the RRB S MAC has bills for payment on laboratory tests for which the A/B MAC (B) has not furnished amounts, it consults with the A/B MAC (B). If necessary the A/B MAC (B) consults with other nearby A/B MACs (B).

110.2 - Coordination With Medicaid
(Rev. 1, 10-01-03)

A/B MACs (B) furnish copies of the fee schedules and the annual update (including NLAs where applicable) to State agencies (SAs). A/B MACs (B) provide updates to SAs at least 30 days prior to the scheduled implementation. To obtain Federal matching funds for clinical laboratory services, State Medicaid agencies may not pay more than Medicare pays for the services and specimen collections.

Since the fee schedule provisions were implemented on a carrier wide basis, a State may have had more than one carrier servicing Medicare beneficiaries residing in the State. A Medicaid agency for such a State may, if it deems necessary, use the fee schedules of either one or both of the A/B MACs (B) to meet the Federal fund-matching requirement. State Medicaid agencies may consult with ROs concerning the fee schedule, the NLAs, and specimen collection provisions.

110.3 - Coordination With A/B MACs (A) and Providers
(Rev. 1, 10-01-03)
HO-437, A3-3628

There may be procedures hospitals bill for outpatients that are not included in the fee schedule. Where gaps occur, hospitals should work out procedures with the A/B MAC (A) so that the hospital can secure the missing information promptly. Price Codes established by the A/B MAC (B) to fill gaps are valid until replaced by the earlier of permanent codes or the next annual update.

110.4 - A/B MAC (B) Contacts With Independent Clinical Laboratories

(Rev. 1, 10-01-03)
B3-2070.1.F

An important role of the A/B MAC (B) is as a communicant of necessary information to independent clinical laboratories. Failure to inform independent laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often must prosecute under a handicap or may refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

To assure that laboratories are aware of Medicare regulations and A/B MAC (B)'s policy, notification must be sent to independent laboratories when any changes are made in coverage policy or claims processing procedures. Additionally, to completely document efforts to fully inform independent laboratories of Medicare policy and the laboratory's responsibilities, previously issued newsletters should be periodically re-issued to remind laboratories of existing requirements.

Some items which should be discussed are the requirements to have the same charges for Medicare and private patients, to document fully the medical necessity for collection of specimens from a skilled nursing facility or a beneficiary's home, and, in cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when A/B MAC (B) professional relations representatives make personal contacts with particular laboratories, they should prepare and retain reports of contact indicating dates, persons present, and issues discussed.

120 - Clinical Laboratory Services Based on the Negotiated Rulemaking

(Rev. 1, 10-01-03)
PM AB-02-129

Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical laboratory services payable under Part B of Medicare. The BBA required that these national policies be designed to promote program integrity and national uniformity; and to simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

These changes apply to every diagnostic clinical laboratory service that is payable under Medicare Part B. Neither the place where the service was performed, nor the type of A/B

MAC (A) or (B) that will process the request for payment, has any effect on the applicability of these policies. A clinical laboratory service done in a hospital laboratory, independent laboratory, physician/practitioner office laboratory or other type of CLIA approved laboratory service is subject to these administrative policies.

The final rule did not affect the requirement that all physician claims must have a diagnosis. If a physician submits a claim for a service performed in a physician office laboratory, that claim is considered a physician claim and must meet the requirements for physician claims.

120.1 - Negotiated Rulemaking Implementation

(Rev. 1769, Issued: 07-10-09, Effective/Implementation: 07-31-09)

The following requirements apply to service providers:

- The date of service should be reported as the date of specimen collection.
- The person obtaining the specimen must furnish the date of collection for the specimen to the entity billing Medicare.
- For specimen collections that span more than a 24-hour period, the date of service should be reported as the date the collection began.
- For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.
- If a situation occurs that does not correspond to the two situations described, the A/B MAC (A) or (B) will submit the question to the RO with the appropriate documentation. The RO will contact the Division of Supplier Claims Processing in CMS, which will serve as the point of contact.

Matching of Diagnosis to Procedure

During claims processing and adjudication, the A/B MAC (A) or (B) adheres to the following:

- If there is a LMRP or NCD for one or more of the services included on the claim, the A/B MAC (A) or (B) reviews all of the diagnosis codes in making a determination regarding medical necessity of the service.
- Even though a claim matches diagnosis to procedure in accordance with an NCD, other rules of adjudication may apply, which could result in denial.
- Diagnoses are required on all claims.

Physicians Reporting Diagnosis Codes When A Diagnostic Test Is Ordered

Section 4317 of the Balanced Budget Act of 1997 provides, with respect to diagnostic laboratory and certain other services, that "if the Secretary (or A/B MAC (A) or (B) of the Secretary) requires the entity furnishing the services to provide diagnostic or other medical information to the entity, the physician or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner." A laboratory or other provider must report on a claim for Medicare payment the diagnostic code(s) furnished by the ordering physician. In the absence of such coding information, the laboratory or other provider may determine the appropriate diagnostic code based on the ordering physician's narrative diagnostic statement or seek diagnostic information from the ordering physician/practitioner. However, a laboratory or other provider may not report on a claim for Medicare payment a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.

Clarification of the Use of the Term "Screening" or "Screen"

The final rule clarifies that effective February 21, 2002, the use of the term "screening" or "screen" in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition. A/B MACs (A) and (B) do not deny a service based solely on the presence of the term "screening" or "screen" in the descriptor.

Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. A/B MACs (A) and (B) have discretionary authority to make reasonable and necessary scope of benefit determinations.

120.2 - Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

(Rev. 3014, Issued: 08-06-14, Effective: ICD-10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Under a negotiated rulemaking process, the Center for Medicare & Medicaid Services (CMS) developed 23 NCDs for clinical diagnostic laboratory services. The NCDs are applicable to services billed under Part B regardless of the entity providing the services. Thus, they are binding on A/B MACs (A and B) in processing clinical diagnostic laboratory services on an outpatient basis.

In order to ensure uniformity in the implementation of the NCDs, CMS developed the NCDs utilizing three lists of diagnosis codes. Every diagnosis code will fall into one the three lists. The lists included: Codes Covered by Medicare, Codes Denied, and Codes That Do Not Support Medical Necessity.

Related software, called the laboratory edit module, is incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation.

In addition, the NCDs are maintained through the NCD process that was announced in the "Federal Register" on September 26, 2003 (68 FR 55634). This process provides for public participation through a comment period at the beginning of the evaluation of the issue and includes a detailed decision document that outlines the rationale for the decision. These documents may be viewed on the Medicare coverage homepage at cms.hhs.gov/coverage.

On a quarterly basis, CMS will update the NCD edit module as necessary for ministerial coding changes and to implement the NCD decisions described above. CMS assures the updated software is communicated to the shared system maintainers. The shared system maintainers install the revised edit module after testing and distribute it to the A/B MACs (A and B) as part of their routine release. A/B MACs (A and B) will conduct provider education to advise the laboratories of changes to the laboratory edit module quarterly.

Exhibit 1 - List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD)

(Rev. 1769, Issued: 07-10-09, Effective/Implementation: 07-31-09)

Refer to section 40.6.2.3 for guidance on the usage of this list.

71010 Chest x-ray
71015 Chest x-ray
71020 Chest x-ray
71021 Chest x-ray
71022 Chest x-ray
71030 Chest x-ray
71035 Chest x-ray
73120 X-ray hand
75710 Artery x-rays, arm/leg
75716 Artery x-rays, arm/leg
75774 Artery x-rays, arms/legs
75790 Artery x-ray, each vessel
75820 Visualize A-V shunt
75822 Vein x-ray, arm/leg
75893 Vein x-ray, arms/legs
75894 Transcath therapy, embolization
75896 X-rays, transcath therapy
75898 X-rays, transcath therapy
75901 Mechanical removal of pericath obstructive material
75902 Mechanical removal of intraluminal obstructive material
75961 Transcath retrieval of intravascular foreign body
75962 Transcath balloon angioplasty
75964 Transcath balloon angioplasty, each additional
76070 Computed tomography, bone mineral density study, axial
76075 Dual energy DEXA, bone density study, axial

76080 Radiologic exam, abscess, fistual or sinus tract study
76092 Screening mammography bilateral
76778 Ultrasound, transplanted kidney
78070 Parathyroid nuclear imaging
78351 Bone density, dual photon absorptionmetry
80048 Basic metabolic panel
80051 Electrolyte panel
80053 Comprehensive Metabolic Panel
? 80061 Lipid panel
80069 Renal function panel
80074 Acute hepatitis panel
80076 Hepatic function panel
80197 Tacrolimus
80410 Calcitonin stim panel
81000 Urinalysis with microscopy
81001 Urinalysis, auto w/scope
81002 Urinalysis nonauto w/o scope
81003 Urinalysis, auto, w/o scope
81005 Urinalysis, qual or semi-quant
81007 Urine screen for bacteria, except by culture or dipstick
81015 Microscopic exam of urine
82009 Test for acetone/ketones,qual
82010 Acetone assay, quant
82017 Acylcarnitines, quant
82040 serum albumin
82042 albumin, urine quant or other source
82108 Assay of aluminum
82232 Beta2microglobulin (monitor large molecular weigh solute clearance by dial
82247 Bilirubin, total
82248 Bilirubin, direct
82306 Assay of vitamin D-3 (calcifediol)
82307 Assay of vitamin D (calciferol)
82308 Assay of calcitonin
82310 Assay of calcium
82330 Assay of calcium, ionized
82374 Bicarbonate (CO2)
82379 Assay of carnitine
82435 Chloride blood (needed to determine acid/base status)
82465 cholesterol, total serum
82550 CPK, total
82565 Assay of creatinine
82570 Assay of urine creatinine
82575 urine creatinine clearance test
82607 Vit B12
82728 ferritin
82746 serum folate
82747 RBC folate
82800 Blood Ggases, ppH onlyy
82803 Blood gases: pH, pO2 & pCO2

82805 Blood gases W/02 saturation
82810 Blood gases, O2 sat only
82945 Glucose other fluid
82947 Assay, glucose, blood quant
82948 Reagent strip/blood glucose
83540 Assay of iron
83550 Iron binding test
83735 magnesium (monitored to avoid hypermagnesium)
83937 Osteocalcin
83970 parathormone (PTH)
83986 Assay of body fluid acidity
84075 alkaline phosphatase
84100 Assay of phosphorus, inorganic
84105 urine phosphorus
84132 Assay of serum potassium
84133 urine potassium
84134 Assay of prealbumin
84155 Assay of protein
84160 serum protein by refractometry
84295 Assay of serum sodium
84315 Body fluid specific gravity
84450 Transferase (AST) (SGOT)
84460 Alanine amino (ALT) (SGPT)
84466 transferrin
84520 Urea nitrogen, quantitative
84540 Assay of urine/urea-n
84545 Urea-N clearance test
84630 zinc
85002 Bleeding time test
85004 Automated diff wbc count
85007 Bl smear w/diff wbc count
85008 Bl smear w/o diff wbc count
85009 Manual diff wbc count b-coat
85013 Spun microhematocrit
85014 Hematocrit
85018 Hemoglobin
85025 Complete CBC w/auto diff wbc
85027 Complete CBC, automated
85032 Manual cell count, each
85041 Automated RBC count
85044 Manual reticulocyte count
85045 Automated reticulocyte count
85046 Reticyte/hgb concentrate
85048 Automated leukocyte count
85049 Automated platelet count
85345 Coagulation time, Lee-White
85347 Coagulation time, activated
85348 Coagulation time, other methods
85520 Heparin assay

85610 Prothrombin time
85611 Prothrombin test,substitution
85651 sed rate
85652 automates sed rate
85730 thromboplastin time, partial (PTT)
85732 Thromboplastin time, partial, substitution
86590 Streptokinase, antibody
86644 CMV screen
86645 Cytomegalovirus antibody dfa (IgM)
86687 HTLV-I antibody
86688 HTLV-II antibody
86689 HTLV/HIV confirmatory test
86692 Hepatitis, delta agent
86701 HIV-1
86702 HIV-2
86703 HIV-1/HIV2, ,singgle assayy
86704 Hep B core antibody, total
86705 Hep b core antibody, IgM
86706 Hep B surface antibody
86707 Hep Be antibody
86709 Hep A, IgM antibody
86803 Hepatitis C ab test
86804 Hep C ab test, confirm
86812 HLA typing, A, B, or C
86813 HLA typing, A, B, or C, multiple antigens
86816 HLA typing, DR/DQ
86817 HLAy tpypignng, DR/DQ, multiple antigens
86900 Blood typing, ABO
86901 Rh typing
86903 Blood typing, antigen screen
86904 Blood typing, patient serum
86905 Blood typing, RBC antigens
86906 Blood typing, Rh phenotype
87040 culture, blood
87070 Culture, bacteria, other
87071 Culture bacteri aerobic other, quant
87073 Culture bacteria anaerobic, quant
87075 Culture bacteria anaerobic, any source w/ID
87076 Culture anaerobe ident, each
87077 Culture aerobic identify
87081 Culture screen only
87084 Culture w/ colony estimation
87086 Urine culture/quant colony count
87088 Urine bacteria culture, isolation & ID
87181 Microbe susceptible, diffuse
87184 Microbe susceptible, disk
87185 Microbe susceptible, enzyme
87186 Microbe susceptible, mic
87187 Microbe susceptible, mlc

87188 Microbe suscept, macrobroth
87190 Microbe suscept, mycobacteri
87197 Bactericidal level, serum
87205 Smear, gram stain
87271 CMV, DFA
87340 HepB surface antigen
87341 HepatitisB surface, ag, eia, neutralization
87350 HepatitisBe ag, eia
87380 Hepatitis delta ag, eia
87390 HIV-1 ag, eia
87391 HIV-2 ag, eia
87515 Hepatitis B, DNA, dir probe
87516 Hepatitis B, DNA, amp probe
87517 Hepatitis B, DNA, quant
87520 Hepatitis C, RNA, dir probe
87521 Hepatitis C, RNA, amp probe
87522 Hepatitis C, RN A, quant
87525 Hepatitis G, DNA, dir probe
87526 Hepatitis G, DNA, amp probe
87527 Hepatitis G, DNA, quant
89050 cell count, peritoneal fluid (no diff)
89051 cell count, peritoneal fluid with diff
93000 Echo exam of heart
93005 Electrocardiogram, tracing
93010 Electrocardiogram report
93040 Rhythm ECG with report
93041 Rhythm ECG, tracing
93042 Rhythm ECG with report
93307 Echo exam of heart
93308 Echo exam of heart, follow-up
93922 Extremity study
93923 Extremity study, multiple levels
93925 Lower extremity study - arterial
93926 Lower extremity study, limited- arterial
93930 Upper extremity study- arterial
93931 Upper extremity study, limited-arterial
93965 Extremity study-venous
93970 Extremity study-venous
93971 Extremity study, limited-venous
G0001 Routine venipuncture
G0202 Screening mammography, digital

180 - Billing for Home Infusion Therapy Services
(Rev. 4112, Issued: 08-10-18, Effective: 01-01-19, Implementation: 01-07-19)

Effective January 1, 2019 and until the implementation of the full home infusion therapy benefit, Medicare makes separate temporary transitional payments for Home Infusion Therapy (HIT) services to eligible home infusion suppliers (i.e., a licensed pharmacy that

provides external infusion pumps and external infusion pump supplies). This payment amount covers the cost of professional services, including nursing services, training and education (not otherwise paid for as durable medical equipment), remote monitoring, and monitoring services for the provision of home infusion therapy furnished by a qualified home infusion with administration of certain transitional home infusion drugs administered through an item of DME.

Temporary transitional payments are made for HIT services based on the home infusion drug provided. Home infusion drugs are assigned to three payment categories, determined by the Healthcare Common Procedure Coding System (HCPCS) J-code. Each DME MAC maintains a list of drugs that are administered through an item of DME and HIT payment is made for days on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration.

Temporary Transitional Payment Categories for Home Infusion Therapy Services, by Infusion Drug (J-Code)

Category 1	
J-Code	**Description**
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg

J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J2278	Injection, ziconotide, 1 microgram
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J-Code	**Description**
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1559 JB	Injection, immune globulin (hizentra), 100 mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J-Code	**Description**
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9200	Injection, floxuridine, 500 mg

J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

The payment category for subsequent transitional home infusion drug additions to the Local Coverage Determinations (LCDs) and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the DME MAC.

A single unit of payment will be made for HIT services provided in the individual's home during an infusion drug administration calendar day.

Suppliers will report the following HCPCS G-codes associated with the payment categories for the professional services furnished in the individual's home and on an infusion drug administration calendar day:

1. G0068: Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each 15 minutes.

   Short Descriptor: Adm of infusion drug in home

2. G0069: Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes.

   Short Descriptor: Adm of immune drug in home

3. G0070: Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes.

   Short Descriptor: Adm of chemo drug in home

In the event that multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, a single payment would be made that is equal to the highest payment category.

Providers should report visit length in 15-minute increments (15 minutes=1 unit). See the table below for the rounding of units.

Rounding of Time Units

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Claims that include G-codes for HIT services are not required to, but may also include the HCPCS J-code for the infusion drug, the E-code for the external infusion pump, and A-codes for supplies other than the drug.

A submitted claim for HIT services is subject to a Common Working File (CWF) edit in the event that a transitional drug J-code is not found on the same claim as the billed professional HIT services, or in claims history in the previous 30 days. If a J-code is not found on the same claim as the billed professional services, the claims processing system will recycle the G-code claim for the professional services associated with the administration of the home infusion drug, until a claim containing the J-code for the infusion drug is received in the CWF. The professional visit claim will recycle three times (with a 30-day look back period) for a total of 15 business days. After 15 business days, if no J-code claim is found in claims history, the G-code claim will be denied.

Suppliers must ensure that the appropriate drug associated with the visit is billed with the visit or no more than 30 days prior to the visit. Visits are denied if the appropriate drug for the visit is not billed. In the event that multiple visits occur on the same date of service, suppliers must only bill for one visit and should report the highest paying visit with the applicable drug. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R4495CP	01/17/2020	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	02/18/2020	11641
	12/20/2019	Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 – Laboratory Date of Service Policy	01/23/2020	11574
	12/20/2019	Internet Only Manual Update to Add New and Revise Sections of Publication 100-04, Chapter 16	01/23/2020	11553
R4299CP	05/03/2019	Re-implementation of the AMCC Lab Panel Claims Payment System Logic	10/07/2019	11248
R4227CP	02/01/2019	Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier	07/01/2019	11061
R4199CP	01/11/2019	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	02/12/2019	11146
R4112CP	11/01/2018	Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020	01/07/2019	10836
R4000CP	03/16/2018	Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 - Date of Service Policy	07/02/2018	10419
R3942CP	12/22/2017	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	01/22/2018	10448
R3875CP	10/06/2017	Internet Only Manual Update to Pub. 100-04, Chapter 16, to update Clinical Lab Fee Schedule Layout	01/08/2018	10195

Rev #	Issue Date	Subject	Impl Date	CR#
R3717CP	02/10/2017	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	05/12/2017	9960
R3685CP	12/22/2016	January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/03/2017	9930
R3619CP	10/07/2016	Table of Chemistry Panels	01/10/2017	9790
R3510CP	04/29/2016	Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages	10/03/2016	9578
R3433CP	12/31/2015	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	02/01/2016	9485
R3425CP	12/18/2015	January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/04/2016	9486
R3255CP	05/08/2015	Correction to the Multi-Carrier System (MCS) Editing on the Service Location National Provider Identifier (NPI) Reported for Anti-Markup and Reference Laboratory Claims	10/05/2015	9150
R3189CP	02/05/2015	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	04/24/2015	9066
R3169CP	01/23/2015	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens – Rescinded and replaced by Transmittal 3189	04/24/2015	9066
R3116CP	11/06/2014	Elimination of the 50/50 Payment Rule for Laboratory Services on End Stage Renal Disease (ESRD) Claims	04/06/2015	8957
R3103CP	11/03/2014	Reporting the Service Location National Provider Identifier (NPI) on Anti-Markup and Reference Laboratory Claims	04/06/2015	8806

Rev #	Issue Date	Subject	Impl Date	CR#
R3098CP	10/21/2014	Reporting the Service Location National Provider Identifier (NPI) on Anti-Markup and Reference Laboratory Claims – Rescinded and replaced by Transmittal 3103	04/05/2014	8806
R3071CP	09/19/2014	Manual Update to Clarify Claims Processing for Laboratory Services	12/22/2014	8883
R3056CP	08/29/2014	Sample Collection Fee Adjustment for Clinical Laboratory Fee Schedule and Laboratory Services	12/01/2014	8837
R3047CP	08/22/2014	Reporting the Service Location National Provider Identifier (NPI) on Anti-Markup and Reference Laboratory Claims – Rescinded and replaced by Transmittal 3098	01/05/2014	8806
R3014CP	08/06/2014	Update to Pub. 100-04, Chapter 16 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/08/2014	8613
R2971CP	05/23/2014	July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/07/2014	8776
R2907CP	03/14/2014	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	06/16/2014	8641
R2904CP	03/14/2014	Update to Pub. 100-04, Chapter 16 to Provide Language-Only Changes for Updating ICD-10 and ASC X12 – Rescinded and replaced by Transmittal 3014	10/01/2014	8613
R2730CP	06/20/2013	Coding Requirements for Laboratory Specimen Collection Update	07/16/2013	8339
R2726CP	06/14/2013	Coding Requirements for Laboratory Specimen Collection Update – Rescinded and replaced by Transmittal 2730	07/16/2013	8339
R2714CP	05/24/2013	Updates to Chapter 12 and Chapter 16 of the Medicare Claims Processing Manual to Revise Instructions Regarding the Technical	06/25/2013	8013

Rev #	Issue Date	Subject	Impl Date	CR#
		Component (TC) of Pathology Services Furnished to Hospital Patients		
R2581CP	11/02/2012	Outpatient Laboratory Services Rendered in a Critical Access Hospital (CAH)	04/01/2013	8025
R2487CP	06/08/2012	Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS)	06/19/2012	7749
R2475CP	05/18/2012	Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS)	06/19/2012	7749
R2136CP	01/21/2011	Medicare and Medicaid Extenders Act of 2010 (MMEA) Extension of Reasonable Cost Payment for Clinical Lab Tests Furnished to Hospitals with Fewer Than 50 Beds in Qualified Rural Areas	07/05/2011	7294
R2106CP	11/24/2010	Calendar Year (CY) 2011 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment	01/03/2011	6991
R1945CP	04/09/2010	New Legislation to Allow Independent Laboratory Billing for the Technical Component of Physician Pathology Services for Hospital Inpatients and Outpatients	07/09/2010	6813
R1940CP	04/02/2010	Extension of Reasonable cost Payment for Clinical lab Tests Furnished by Hospitals With Fewer Than 50 Beds in Qualified Rural Areas	07/06/2010	6873
R1884CP	12/23/2009	Calendar Year (CY) 2010 Annual Update for Clinical Laboratory Fee Schedule and	01/04/2010	6657

Rev #	Issue Date	Subject	Impl Date	CR#
		Laboratory Services Subject to Reasonable Charge Payment		
R1782CP	07/30/2009	Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA)	07/06/2009	6395
R1769CP	07/10/2009	ESRD: Placement of a List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD)	07/31/2009	6515
R1763CP	07/02/2009	ESRD: Placement of a List of Diagnostic Tests that are Considered End Stage Renal Disease (ESRD) – Rescinded and replaced by Transmittal 1769	07/02/2009	6515
R1729CP	05/08/2009	Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA) - Rescinded and replaced by Transmittal 1782	07/06/2009	6395
R1712CP	04/17/2009	Section 148 of the Medicare Improvements for Patients and Providers Act (MIPPA) - Rescinded and replaced by Transmittal 1729	07/06/2009	6395
R1690CP	02/27/2009	Reporting the National Provider Identifier (NPI) on Claims for Reference Laboratory and Purchased Diagnostic Services Performed Outside the Billing Jurisdiction	03/27/2009	6362
R1655CP	12/31/2008	End Stage Renal Disease (ESRD) Medicare Claims Processing Manual Clarification	02/02/2009	6245
R1652CP	12/19/2008	New Waived Tests	01/05/2009	6287
R1584CP	09/05/2008	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens	10/06/2008	6195
R1561CP	07/25/2008	Medicare Improvements for Patients and Providers Act of 2008- Legislative Change Concerning Independent Laboratory Billing for the Technical Component of Physician Pathology Services	08/25/2008	6042

Rev #	Issue Date	Subject	Impl Date	CR#
R1524CP	05/30/2008	Clinical Laboratory Fee Schedule-Medicare Travel Allowance Fees for Collection of Specimens	06/30/2008	5996
R1515CP	05/23/2008	Date of Service (DOS) for Clinical Laboratory and Pathology Specimens	01/05/2009	6018
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1451CP	02/15/2008	Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm	07/07/2008	5874
R1445CP	02/08/2008	January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)-Manualization	03/10/2008	5946
R1440CP	02/07/2008	Medicare, Medicaid, and SCHIP Extension Act of 2007 Changes to Independent Laboratory Billing for the Technical Component of Physician Pathology Services	03/07/2008	5943
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1319CP	08/17/2007	Date of Service for Laboratory Specimens	01/01/2008	5573
R1221CP	04/18/2007	Common Working File (CWF) Duplicate Claim Edit for the Technical Component (TC) of Radiology and Pathology Laboratory Services Provided to Hospital Patients	04/02/2007	5347
R1098CP	11/03/2006	Common Working File (CWF) Duplicate Claim Edit for the Technical Component (TC) of Radiology and Pathology Laboratory Services Provided to Hospital Patients Replace by Transmittal 1221	04/02/2007	5347
R865CP	02/17/2006	Health Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits	07/03/2006	4321

Rev #	Issue Date	Subject	Impl Date	CR#
R852CP	02/10/2006	Ambulance Fee Schedule – CY 2006 Update: Correction to CR 4061	02/24/2006	4362
R800CP	12/30/2005	Clinical Diagnostic Laboratory Date of Service (DOS) for Archived Specimens	04/03/2006	4156
R795CP	12/30/2005	Redefined Type of Bill (TOB) 14X for Non-Patient Laboratory Specimens-CR 3835 Manualization	04/03/2006	4208
R744CP	11/04/2005	File Descriptions and Instructions for Retrieving the 2006 Fee Schedules and HCPCS through CMS's Mainframe Telecommunications System	01/03/2006	4084
R734CP	10/28/2005	Redefined Type of Bill (TOB), 14x, for Non-Patient Laboratory Specimens	04/03/2006	3835
R733CP	10/28/2005	Repeat Tests for Automated Multi-Channel Chemistries for End Stage Renal Disease Beneficiaries	04/03/2006	4101
R598CP	06/27/2005	Implementation of Carrier Guidelines for End Stage Renal Disease (ESRD) Reimbursement for Automated Multi-Channel Chemistry (AMCC) Tests	01/01/2006	3890
R595CP	06/24/2005	Implementation of Carrier Guidelines for End Stage Renal Disease (ESRD) Reimbursement for Automated Multi-Channel Chemistry (AMCC) Tests	07/25/2005	3890
R372CP	11/19/2004	Payment for Referred Laboratory Automated Multi-Channel Chemistry (AMCC) Tests	04/04/2005	3483
R289CP	08/27/2004	File Descriptions and Instructions for Retrieving 2004 Pricing Files	01/03/2005	3428
R198CP	06/04/2004	AMCC tests for ESRD-related lab services	01/03/2005	2813
R164CP	04/30/2004	Replaced by Rev 198CP	06/04/2004	2813
R102CP	02/20/2004	New waived tests approved by the Food and Drug Administration under Clinical	04/05/2004	3061

Rev #	Issue Date	Subject	Impl Date	CR#
		Laboratory Improvement Amendments of 1988		
R100CP	02/13/2004	Outpatient Clinical Laboratory Tests Furnished by Hospitals with Fewer than 50 beds in Qualified Rural Areas for cost reporting periods beginning during the 2-year period beginning on July 1, 2004.	07/06/2004	3130
R085CP	02/06/2004	Pricing payment for referred services based upon zip code of where the service was performed	07/06/2004	3090
R079CP	02/06/2004	ESRD Reimbursement for AMCC Tests	07/06/2004	2813
R071CP	01/23/2004	Quarterly updates for NCD edit module for clinical diagnostic lab services	04/05/2004	3032 & 3072
R069CP	01/23/2004	Deletion of requirement to validate that the ESRD beneficiary is in a SNF Part A stay	02/23/2004	2906
R023CP	10/31/2003	Pricing payment for referred services based upon zip code of where the service was performed	4/5/2004	2193
R016CP	10/31/2003	Fee schedule payment for independent laboratories for the technical component of a purchased diagnostic service	04/05/2004	2919
R012CP	10/24/2003	Claims for fecal leukocyte examinations	01/01/2004	2924
R001CP	10/01/2003	Initial Publication of Manual	NA	NA

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EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

STATE OF GEORGIA *ex rel.* HUNTER LABORATORIES, LLC and CHRIS RIEDEL, an individual, Plaintiff, v. QUEST DIAGNOSTICS INCORPORATED, QUEST DIAGNOSTICS NICHOLS INSTITUTE f/k/a QUEST DIAGNOSTICS, INC., QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC., LABORATORY CORPORATION OF AMERICA, LABORATORY CORPORATION OF AMERICA HOLDINGS, and SPECIALTY LABORATORIES, INC., et al., Defendants.	)	CIVIL ACTION NO. _____

DEFENDANTS' JOINT NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1331, 1367, 1441, 1446 and other applicable law, Defendants Quest Diagnostics Incorporated, Quest Diagnostics Nichols Institute, Quest Diagnostics Clinical Laboratories, Inc., and Specialty Laboratories, Inc. (together, "Quest"), along with Defendants Laboratory Corporation of America and Laboratory Corporation of America Holdings (together, "LabCorp"), hereby

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *ex rel.* **CHRIS RIEDEL**, an individual,

2605 South Winchester Boulevard
Campbell, CA 95008

Plaintiffs,

vs.

BOSTON HEART DIAGNOSTICS CORPORATION, a Delaware corporation;

175 Crossing Blvd. Suite 550
Framingham, MA 01701-4163

Defendant.

Civil Case No. _____

COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE FALSE CLAIMS ACT

DEMAND FOR JURY TRIAL

[FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *ex rel.* **CHRIS RIEDEL**, an individual, 2605 South Winchester Boulevard Campbell, CA 95008 Plaintiffs, vs. **HEALTH DIAGNOSTIC LABORATORY, INC.**, a Virginia corporation; 737 N. 5th Street, Suite 103 Richmond, VA 23219 **BLUEWAVE HEALTHCARE CONSULTANTS, INC.**, an Alabama corporation; 307 Commercial Street SE Hanceville, AL 35077 and **SINGULEX, INC.**, a Delaware corporation, 1650 Harbor Bay Parkway, Suite 200 Alameda, CA 94502 Defendants.	Civil Case No. _____

COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES FOR VIOLATIONS OF THE FALSE CLAIMS ACT

DEMAND FOR JURY TRIAL

[FILED ~~IN CAMERA AND~~ UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)]

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

COMMONWEALTH OF VIRGINIA *ex rel.* HUNTER LABORATORIES, LLC and CHRIS RIEDEL, an individual,

Plaintiff,

v.

QUEST DIAGNOSTICS INCORPORATED, QUEST DIAGNOSTICS NICHOLS INSTITUTE f/k/a QUEST DIAGNOSTICS, INC., QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC., LABORATORY CORPORATION OF AMERICA, LABORATORY CORPORATION OF AMERICA HOLDINGS, and SPECIALTY LABORATORIES, INC., et al.,

Defendants.

CIVIL ACTION NO. _____

1:13cv1129
GBL/TCB

QUEST DIAGNOSTICS INCORPORATED, QUEST DIAGNOSTICS NICHOLS INSTITUTE, AND QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.'S NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1331, 1367, 1441, 1446 and other applicable law, Defendants Quest Diagnostics Incorporated, Quest Diagnostics Nichols Institute, and Quest Diagnostics Clinical Laboratories, Inc. (collectively, "Quest") hereby file this Notice of Removal of the above-captioned case. Quest respectfully asserts the following facts to support removal, and in so doing, expressly reserves all other issues for further pleadings.

EXHIBIT H

Alex Padilla
California Secretary of State

Business Entities (BE)

- Online Services
  - File LLC Statement of Information
  - File Corporation Statement of Information
  - Business Search
  - Publicly Traded Disclosure Search
  - Current Processing Dates
- Service Options
- Name Availability
- Forms, Samples & Fees
- Statements of Information (annual/biennial reports)
- Filing Tips
- Information Requests (certificates, copies & status reports)
- Service of Process
- FAQs
- Contact Information
- Resources

Business Search - Entity Detail

The California Business Search is updated daily and reflects work processed through Sunday, May 17, 2020. Please refer to document **Processing Times** for the received dates of filings currently being processed. The data provided is not a complete or certified record of an entity. Not all images are available online.

201526710052 STF, LLC

Registration Date:	09/22/2015
Jurisdiction:	CALIFORNIA
Entity Type:	DOMESTIC
Status:	ACTIVE
Agent for Service of Process:	JON MICHAELSON 1080 MARSH RD MENLO PARK CA 94025
Entity Address:	1080 MARSH RD MENLO PARK CA 94025
Entity Mailing Address:	1080 MARSH RD MENLO PARK CA 94025
LLC Management	Managers

A Statement of Information is due EVERY ODD-NUMBERED year beginning five months before and through the end of September.

Document Type	File Date	PDF
SI-NO CHANGE	04/22/2020	
SI-COMPLETE	03/04/2016	
REGISTRATION	09/22/2015	

Business Resources
Tax Information
Starting A Business Checklist
FTB Nonprofit Dissolution
FTB Administrative Dissolution/Surrender Notice
FTB Abatement
Customer Alerts
Business Identity Theft
Misleading Business Solicitations

Related Links

Legislation
California Codes
California Regulations
Private Service Companies

* Indicates the information is not contained in the California Secretary of State's database.

Note: If the agent for service of process is a corporation, the address of the agent may be requested by ordering a status report.

- For information on checking or reserving a name, refer to **Name Availability**.
- If the image is not available online, for information on ordering a copy refer to **Information Requests**.
- For information on ordering certificates, status reports, certified copies of documents and copies of documents not currently available in the Business Search or to request a more extensive search for records, refer to **Information Requests**.
- For help with searching an entity name, refer to **Search Tips**.
- For descriptions of the various fields and status types, refer to **Frequently Asked Questions**.

Modify Search | New Search | Back to Search Results

Secretary of State
Statement of No Change
(Limited Liability Company)

LLC-12NC

20-B74499

FILED

In the office of the Secretary of State
of the State of California

APR 22, 2020

This Space For Office Use Only

IMPORTANT — Read instructions before completing this form. This form may be used only if a complete Statement of Information has been filed previously and there has been no change.

Filing Fee – $20.00

Copy Fee – $1.00;
Certification Fee - $5.00 plus copy fee

1. Limited Liability Company Name (Enter the **exact** name of the LLC as it is recorded with the California Secretary of State. Note: If you registered in California using an alternate name, see instructions.)

STF, LLC

2. 12-Digit Secretary of State File Number

201526710052

3. State, Foreign Country or Place of Organization (only if formed outside of California)

CALIFORNIA

4. No Change Statement (Do not alter the No Change Statement. If there has been any change, please complete a Statement of Information (Form LLC-12).)

There has been no change in any of the information contained in the previous complete Statement of Information filed with the California Secretary of State.

5. The information contained herein is true and correct.

04/22/2020	Chris Riedel	manager	
Date	Type or Print Name of Person Completing the Form	Title	Signature

Return Address (Optional) (For communication from the Secretary of State related to this document, or if purchasing a copy of the filed document, enter the name of a person or company and the mailing address. This information will become public when filed. (SEE INSTRUCTIONS BEFORE COMPLETING.)

Name:
Company:
Address:
City/State/Zip: